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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
EUREKA-MCKINLEYVILLE

HUMBOLDT COUNTY, CALIFORNIA Plaintiff, v. PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; TEVA PHARMACEUTICALS INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.;	No. COMPLAINT JURY TRIAL DEMANDED

ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC; MALLINCKRODT PLC; MALLINCKRODT, LLC; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; AMERISOURCEBERGEN DRUG CORPORATION; and JOHN AND JANE DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

TABLE OF CONTENTS

I. INTRODUCTION

1. The United States is experiencing the worst man-made epidemic in modern medical history-the misuse, abuse, and over-prescription of opioids.

2. Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose, more than five times as many American lives as were lost in the entire Vietnam War. On any given day, 145 people will die from opioid overdoses in the United States. Drug overdoses are now the leading cause of death for Americans under age fifty.

3. The opioid crisis has become a public health emergency of unprecedented levels. Plaintiff Humboldt County, in California State, with approximately 136,000 residents, has been deeply affected by the crisis. In 2016, Humboldt County had the second highest opioid overdose rate in California, with thirty-three lives lost to opioids that year alone.[1] The opioid abuse prevalent throughout the County has affected Plaintiff in numerous ways, not only through the need for increased emergency medical services, but also through increased drug-related offenses affecting law enforcement, corrections, and courts, and through additional resources spent on community and social programs, including for the next generation of Humboldt residents, who are growing up in the shadow of the opioid epidemic.

4. Humboldt County has been working on confront the epidemic caused by Defendants' reckless promotion and distribution of prescription opioids. The County spends substantial amounts of its budget on treatment and harm reduction programs, and its commitment to address the opioid crisis head-on has kept the overdose death toll from climbing even higher.

5. But although Humboldt County has devoted considerable resources to address the opioid crisis, to fully address the crisis will require the County to spend resources it does not have. It would be unfair to require Humboldt County to bear all the costs of addressing an epidemic caused by Defendants' intentional conduct. Rather, those responsible for the opioid crisis should pay to abate the nuisance and harms they have created in Humboldt County.

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[1] Sam Armanino, *Report: more opioid prescriptions in Humboldt County than residents*, Times Standard (Oct. 26, 2017, 9:11PM), http://www.times-standard.com/article/NJ/20171026/NEWS/171029864.

6. The opioid epidemic is no accident. On the contrary, it is the foreseeable consequence of Defendants' reckless promotion and distribution of potent opioids for chronic pain while deliberately downplaying the significant risks of addiction and overdose.

7. Defendant Purdue set the stage for the opioid epidemic, through the production and promotion of its blockbuster drug, OxyContin. Purdue introduced a drug with a narcotic payload many times higher than that of previous prescription painkillers, while executing a sophisticated, multi-pronged marketing campaign to change prescribers' perception of the risk of opioid addiction and to portray opioids as effective treatment for chronic pain. Purdue pushed its message of opioids as a low-risk panacea on doctors and the public through every available avenue, including through direct marketing, front groups, key opinion leaders, unbranded advertising, and hundreds of sales representatives who visited doctors and clinics on a regular basis.

8. As sales of OxyContin and Purdue's profits surged, Defendants Endo, Janssen, Cephalon, Actavis, and Mallinckrodt—as explained in further detail below—added additional prescription opioids, aggressive sales tactics, and dubious marketing claims of their own to the deepening crisis. They paid hundreds of millions of dollars to market and promote the drugs, notwithstanding their dangers, and pushed bought-and-paid-for "science" supporting the safety and efficacy of opioids that lacked any basis in fact or reality. Obscured from the marketing was the fact that prescription opioids are not much different than heroin-indeed on a molecular level, they are virtually indistinguishable.

9. The opioid epidemic simply could not have become the crisis it is today without an enormous supply of pills. Defendants McKesson, Cardinal Health, and AmerisourceBergen raked in huge profits from the distribution of opioids around the United States. These companies knew precisely the quantities of potent narcotics they were delivering to communities across the country, including Humboldt County. Yet not only did they intentionally disregard their monitoring and reporting obligations under federal law, they also actively sought to evade restrictions and obtain higher quotas to enable the distribution of even larger shipments of opioids.

10. Defendants' efforts were remarkably successful: since the mid-1990s, opioids have become the most prescribed class of drugs in America. Between 1991 and 2011, opioid prescriptions in the United States tripled from 76 million to 219 million per year.[2] In 2013, health care providers wrote more than 249 million prescriptions for opioid pain medication, enough for every adult in the United States to have more than one bottle of pills.[3] In terms of annual sales, the increase has been ten-fold; before the FDA approved OxyContin in 1995, annual opioid sales hovered around $1 billion. By 2015, they increased to almost $10 billion. By 2020, revenues are projected to grow to $18 billion.[4]

11. But Defendants' profits have come at a steep price. Opioids are now the leading cause of accidental death in the United States, surpassing deaths caused by car accidents. Opioid overdose deaths (which include prescription opioids as well as heroin) have risen steadily every year, from approximately 8,048 in 1999, to 20,422 in 2009, to over 33,091 in 2015. In 2016, that toll climbed to 42,249.[5]

12. To put these numbers in perspective: in 1970, when a heroin epidemic swept the United States, there were fewer than 3,000 heroin overdose deaths. And in 1988, around the height of the crack epidemic, there were fewer than 5,000 crack overdose deaths recorded. In 2005, at its peak, methamphetamine was involved in approximately 4,500 deaths.

13. As shown in the graph below, the recent surge in opioid-related deaths involves

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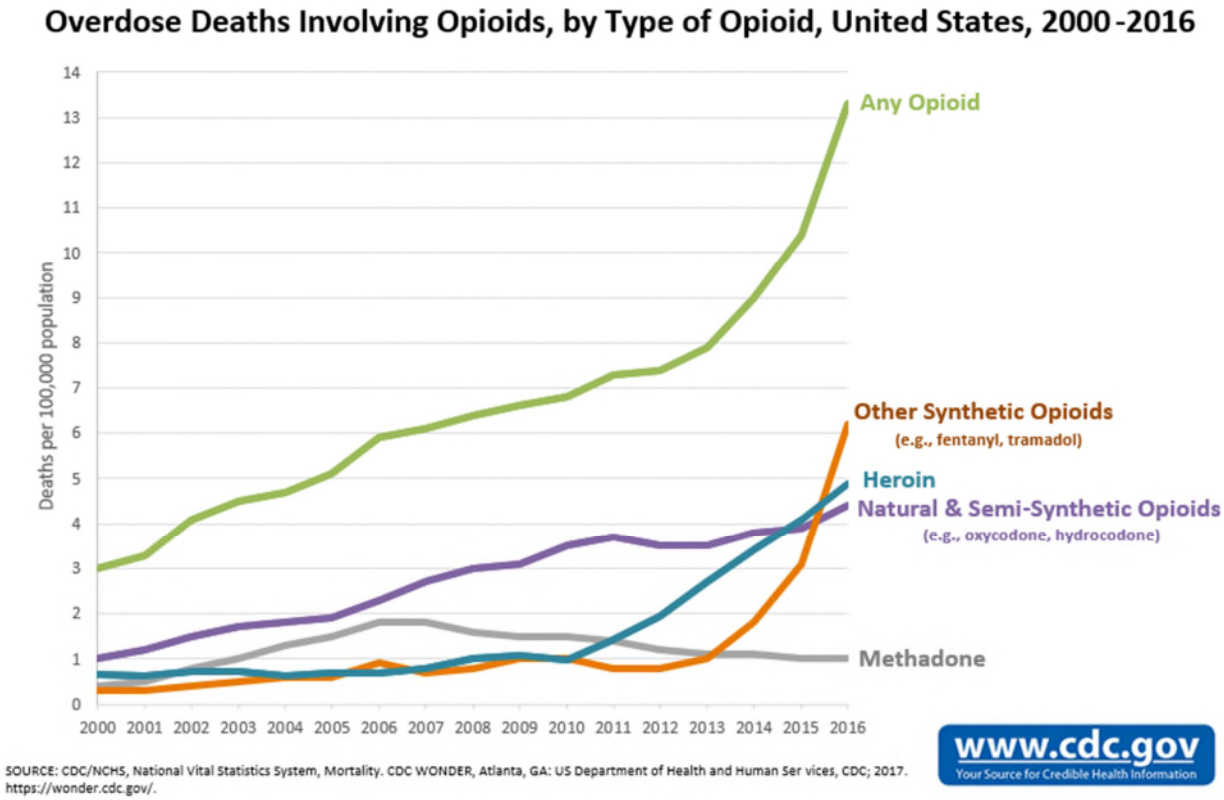
[2] Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before the Senate Caucus on International Narcotics Control, NIH Nat'l Inst. on Drug Abuse (May 14, 2014), https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

[3] *CDC Guideline for Prescribing Opioids for Chronic Pain*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf (last visited July 17, 2018).

[4] *Report: Opioid pain sales to hit $18.4B in the U.S. by 2020*, CenterWatch (July 17, 2017), https://www.centerwatch.com/news-online/2017/07/17/report-opioid-pain-sales-hit-18-4b-u-s-2020/#more-31534.

[5] *Overdose Death Rates*, NIH Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (revised Sept. 2017); *Drug Overdose Death Data*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated December 19, 2017).

prescription opioids, heroin, and other synthetic opioids. Nearly half of all opioid overdose deaths involve a prescription opioid like those manufactured by Defendants,[6] and the increase in overdoses from non-prescription opioids is directly attributable to Defendants' success in expanding the market for opioids of any kind.



14. Just as it has nationally, the opioid epidemic in Humboldt County has exacted a grim toll. Between 2012 and 2016, at least 132 residents of Humboldt County died from opioid-related overdoses.[7]

15. Beyond the human cost, the CDC recently estimated that the total economic burden of prescription opioid abuse costs the United States $78.5 billion per year, which includes increased costs for health care and addiction treatment, increased strains on human services and

[6] *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).

[7] *Humboldt County, CA*, NACo County Explorer, http://explorer.naco.org/ (last visited July 17, 2018).

criminal justice systems, and substantial losses in workforce productivity.[8]

16. But even the available estimates of the economic burden of the opioid epidemic are conservative. The Council of Economic Advisers—the primary advisor to the Executive Office of the President—recently issued a report estimating that "in 2015, the economic cost of the opioid crisis was $504.0 billion, or 2.8% of GDP that year. This is over six times larger than the most recently estimated economic cost of the epidemic."[9] Whatever the final tally, there is no doubt that this crisis has had a profound economic impact.

17. Defendants orchestrated this crisis. Despite knowing about the true hazards of their products, Defendants misleadingly advertised their opioids as safe and effective for treating chronic pain and pushed hundreds of millions of pills into the marketplace for consumption. Through their sophisticated and well-orchestrated marketing campaigns, Defendants exaggerated the benefits of opioids to treat pain and downplayed the risk of addiction. Moreover, even as the deadly toll of prescription opioid use became apparent to Defendants in years following OxyContin's launch, Defendants persisted in aggressively selling and distributing prescription opioids, while evading their monitoring and reporting obligations, so that massive quantities of addictive opioids continued to pour into Humboldt County and other communities around the United States.

18. Defendants consistently, deliberately, and recklessly made and continue to make false and misleading statements regarding, among other things, the low risk of addiction to opioids, opioids' efficacy for chronic pain and ability to improve patients' quality of life with long-term use, the lack of risk associated with higher dosages of opioids, the need to prescribe more opioids to treat withdrawal symptoms, and that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids.

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[8] *CDC Foundation's New Business Pulse Focuses on Opioid Overdose Epidemic*, Ctrs. for Disease Control and Prevention (Mar. 15, 2017), https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html.

[9] *The Underestimated Cost of the Opioid Crisis*, The Council of Econ. Advisers (Nov. 2017), https://static.politico.com/1d/33/4822776641cfbac67f9bc7dbd9c8/the-underestimated-cost-of-the-opioid-crisis-embargoed.pdf.

19. Because of Defendants' misconduct, Humboldt County is experiencing a severe public health crisis and has suffered significant economic damages, including but not limited to increased costs related to public health, opioid-related crimes and emergencies, health care, criminal justice, social services, child welfare, and public safety. Humboldt County has incurred substantial costs in responding to the crisis and will continue to do so in the future.

20. Accordingly, Humboldt County brings this action to hold Defendants liable for their misrepresentations regarding the benefits and risks of opioids, as well as for their failure to monitor, detect, investigate, and report suspicious orders of prescription opioids. This conduct (i) violates California's Unfair Competition Law, (ii) constitutes a public nuisance under California law, (iii) constitutes negligence and gross negligence under California law, (iv) has unjustly enriched Defendants, and (v) violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq*.

II. PARTIES

Humboldt County

21. Plaintiff Humboldt County ("Humboldt County" or "County") is a California county.

Purdue

22. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. Collectively, these entities are referred to as "Purdue."

23. Each Purdue entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

24. Purdue manufactures, promotes, sells, markets, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including in Humboldt County.

25. Purdue generates substantial sales revenue from its opioids. For example,

OxyContin is Purdue's best-selling opioid, and since 2009, Purdue has generated between $2 and $3 billion annually in sales of OxyContin alone

Endo

26. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business in Malvern, Pennsylvania. Collectively, these entities are referred to as "Endo."

27. Each Endo entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

28. Endo manufactures, promotes, sells, markets, and distributes opioids such as Percocet, Opana, and Opana ER in the United States, including in Humboldt County.

29. Endo generates substantial sales from its opioids. For example, opioids accounted for more than $400 million of Endo's overall revenues of $3 billion in 2012, and Opana ER generated more than $1 billion in revenue for Endo in 2010 and 2013.

Janssen and Johnson & Johnson

30. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Collectively, these entities are referred to as "Janssen."

31. Both entities above acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

32. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

33. Janssen manufactures, promotes, sells, markets, and distributes opioids such as Duragesic, Nucynta, and Nucynta ER in the United States, including in Humboldt County. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

34. Janssen generates substantial sales revenue from its opioids. For example, Duragesic accounted for more than $1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

Cephalon and Teva

35. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation and a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

36. Cephalon manufactures, promotes, sells, and distributes opioids, including Actiq and Fentora, in the United States.

37. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon-branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which are distributed with Cephalon opioids, disclose that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

38. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[10] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012—the year following the Cephalon acquisition in October 2011—attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including sales of Fentora.[11] Through interrelated

[10] Actiq, http://www.actiq.com/ (last visited July 17, 2018).

[11] *Teva Pharm. Indus. Ltd. Form 20-F*, U.S. Sec. and Exchange Commission (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva Ltd. would conduct those companies' business in the United States itself.

39. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Collectively, these entities are referred to as "Cephalon."

Allergan, Actavis, and Watson

40. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company changed its name to Allergan plc in June 2015. Actavis plc (formerly known as Actavis Limited) was incorporated in Ireland in May 2013 for the merger between Actavis, Inc. and Warner Chilcott plc.

41. Defendant Watson Pharmaceuticals, Inc. acquired Actavis Group in October 2012 and changed its name to Actavis, Inc. as of January 2013.

42. Defendant Allergan Finance, LLC (formerly known as Actavis, Inc.) is based in Parsippany, New Jersey. It operates as a subsidiary of Allergan plc.

43. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

44. Defendant Actavis Pharma, Inc. is registered to do business with the California Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

45. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

46. Each of these defendants and entities is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Upon information and belief, Defendant Allergan plc exercises control over these marketing and sales efforts and profits from

the sale of Allergan/Actavis/Watson products ultimately inure to its benefit. Collectively, these defendants and entities are referred to as "Actavis."

47. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco and generic versions of Kadian, Duragesic, and Opana in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

Mallinckrodt

48. Defendant Mallinckrodt plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt began as a U.S.-based company, with the founding of Mallinckrodt & Co. in 1867; Tyco International Ltd. acquired the company in 2000. In 2008, Tyco Healthcare Group separated from Tyco International and renamed itself Covidien.

49. Defendant Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware and licensed to do business in California. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt plc. Mallinckrodt plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

50. Mallinckrodt manufactures, markets, and sells drugs in the United States. As of 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the largest manufacturers of oxycodone in the U.S.

51. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths.

52. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health

data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

53. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

54. In 2017, Mallinckrodt agreed to settle for $35 million the Department of Justice's allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged that even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA").

55. Defendants Purdue, Endo, Janssen, Cephalon, Actavis, and Mallinckrodt are collectively referred to as the "Manufacturing Defendants."

AmerisourceBergen

56. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania.

57. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest global pharmaceutical sourcing and distribution services companies" with "over $145 billion in annual revenue."

58. AmerisourceBergen is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs in California State, including opioids. It operates distribution centers in Sacramento, Corona, and Valencia, California.

Cardinal Health

59. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its principal place of business in Dublin, Ohio.

60. According to its 2017 Annual Report, Cardinal Health is "a global, integrated

healthcare services and products company serving hospitals, healthcare systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide . . . deliver[ing] medical products and pharmaceuticals." In 2017 alone, Cardinal Health generated revenues of nearly $130 billion.

61. Cardinal Health is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs in California State, including opioids. It operates distribution centers in Elk Grove and Valencia, California.

McKesson

62. Defendant McKesson Corporation ("McKesson") is a Delaware Corporation with its principal place of business in San Francisco, California.

63. McKesson is the largest pharmaceutical distributor in North America, delivering nearly one-third of all pharmaceuticals used in this region.

64. According to its 2017 Annual Report, McKesson "partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively." Additionally, McKesson's pharmaceutical distribution business operates and serves thousands of customer locations through a network of twenty-seven distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all fifty states and Puerto Rico.

65. For the fiscal year ending March 31, 2017, McKesson generated revenues of $198.5 billion.

66. McKesson is licensed as a "wholesale distributor" to sell prescription and non-prescription drugs in California State, including opioids. It operates distribution centers in Sacramento and Santa Fe Springs, California.

67. Collectively, McKesson, AmerisourceBergen, and Cardinal Health (together "Distributor Defendants") account for approximately 85% of all drug shipments in the United States.

John and Jane Does 1-100, inclusive

68. In addition to the Defendants identified herein, the true names, roles, and/or capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under fictitious names as permitted by the rules of this Court. Plaintiff will amend this complaint and identify their true identities and their involvement in the wrongdoing at issue, as well as the specific causes of action asserted against them when they become known.

III. JURISDICTION AND VENUE

69. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The Court also has federal question subject matter jurisdiction arising out of Plaintiff's RICO claims pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq*.

70. Venue in this Court is proper under 28 U.S.C. § 1391(b).

IV. FACTUAL ALLEGATIONS

A. Making an Old Drug New Again

1. A history and background of opioids in medicine

71. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids.[12] Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression. In addition, opioids cause sedation and constipation.

72. Most of these effects are medically useful in certain situations, but respiratory depression is the primary limiting factor for the use of opioids. While the body develops tolerance to the analgesic and euphoric effects of opioids relatively quickly, this is not true with respect to respiratory depression. At high doses, opioids can and often do arrest respiration

[12] At one time, the term "opiate" was used for natural opioids, while "opioid" referred to synthetic substances manufactured to mimic opiates. Now, however, most medical professionals use "opioid" to refer broadly to natural, semi-synthetic, and synthetic opioids. A fourth class of opioids, endogenous opioids (e.g., endorphins), is produced naturally by the human body.

altogether. This is why the risk of opioid overdose is so high, and why many of those who overdose simply go to sleep and never wake up.

73. Natural opioids are derived from the opium poppy and have been used since antiquity, going as far back as 3400 B.C. The opium poppy contains various opium alkaloids, three of which are used commercially today: morphine, codeine, and thebaine.

74. A 16th-century European alchemist, Paracelsus, is generally credited with developing a tincture of opium and alcohol called laudanum, but it was a British physician a century later who popularized the use of laudanum in Western medicine. "Sydenham's laudanum" was a simpler tincture than Paracelsus's and was widely adopted as a treatment not only for pain, but for coughs, dysentery, and numerous other ailments. Laudanum contains almost all of the opioid alkaloids and is still available by prescription today.

75. Chemists first isolated the morphine and codeine alkaloids in the early 1800s, and the pharmaceutical company Merck began large-scale production and commercial marketing of morphine in 1827. During the American Civil War, field medics commonly used morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. It was upper and middle class white women, however, who comprised the majority of opioid addicts in the late 19th-century United States, using opioid preparations widely available in pain elixirs, cough suppressants, and patent medicines. By 1900, an estimated 300,000 people were addicted to opioids in the United States,[13] and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms.

76. Trying to develop a drug that could deliver opioids' potent pain relief without their addictive properties, chemists continued to isolate and refine opioid alkaloids. Heroin, first synthesized from morphine in 1874, was marketed commercially by the Bayer Pharmaceutical Company beginning in 1898 as a safe alternative to morphine. Heroin's market position as a safe alternative was short-lived, however; Bayer stopped mass-producing heroin in 1913 because of

[13] Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*, Washington Post (Oct. 17, 2017), https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca.

its dangers. German chemists then looked to the alkaloid thebaine, synthesizing oxymorphone and oxycodone from thebaine in 1914 and 1916, respectively, with the hope that the different alkaloid source might provide the benefits of morphine and heroin without the drawbacks.

77. But each opioid was just as addictive as the one before it, and eventually the issue of opioid addiction could not be ignored. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows . . . it has become one of the most fertile causes of unhappiness and sin in the United States."[14]

78. Concerns over opioid addiction led to national legislation and international agreements regulating narcotics: the International Opium Convention, signed at the Hague in 1912, and, in the U.S., the Harrison Narcotics Tax Act of 1914. Opioids were no longer marketed as cure-alls and instead were relegated to the treatment of acute pain.

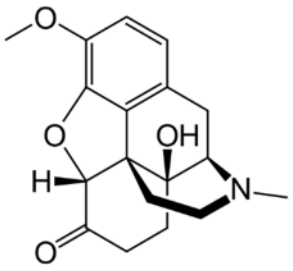
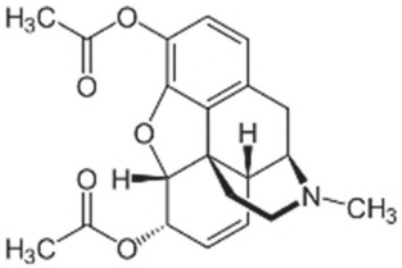
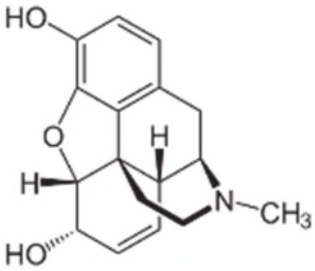
79. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids, but these opioids were generally produced in combination with other drugs, with relatively low opioid content. For example, Percodan, produced by Defendant Endo since 1950, is oxycodone and aspirin, and contains just under 5 mg of oxycodone. Percocet, manufactured by Endo since 1971, is the combination of oxycodone and acetaminophen, with dosage strengths delivering between 2.5 mg and 10 mg of oxycodone. Vicodin, a combination of hydrocodone and acetaminophen, was introduced in the U.S. in 1978 and is sold in strengths of 5 mg, 7.5 mg, and 10 mg of hydrocodone. Defendant Janssen also manufactured a drug with 5 mg of oxycodone and 500 mg of acetaminophen, called Tylox, from 1984 to 2012.

80. In contrast, OxyContin, the product with the dubious honor of the starring role in the opioid epidemic, is pure oxycodone. Purdue initially made it available in the following dosage strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. In other

[14] *Id.*

words, the weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times as much as that.

81. Prescription opioids are essentially pharmaceutical heroin; they are synthesized from the same plant, have similar molecular structures, and bind to the same receptors in the human brain. It is no wonder then that there is a straight line between prescription opioid abuse and heroin addiction. Indeed, studies show that over 80% of new heroin addicts between 2008 and 2010 started with prescription opioids.[15]

Oxycodone	Heroin	Morphine
		

82. Medical professionals describe the strength of various opioids in terms of "morphine milligram equivalents" ("MME"). According to the CDC, dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

83. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin's twice-daily dosing, the 50 MME/day threshold is reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.[16]

[15] Jones CM, Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers - United States, 2002-2004 and 2008-2010, 132(1-2) Drug Alcohol Depend. 95-100 (Sept. 1, 2013), https://www.ncbi.nlm.nih.gov/pubmed/23410617.

[16] The wide variation in the MME strength of prescription opioids renders misleading any effort to capture "market share" by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills,

84. As journalist Barry Meier wrote in his 2003 book *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death*, "In terms of narcotic firepower, OxyContin was a nuclear weapon."[17]

85. Fentanyl, an even more potent and more recent arrival in the opioid tale, is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959 by Dr. Paul Janssen under a patent held by Janssen Pharmaceutical, fentanyl is increasingly prevalent in the market for opioids created by Defendants' promotion, with particularly lethal consequences. In many instances, illicit fentanyl is manufactured to look like oxycodone tablets, in the light blue color and with the "M" stamp of Defendant Mallinckrodt's 30mg oxycodone pills. These lookalike pills have been found around the country, including in California State.[18]

2. The Sackler family pioneered the integration of advertising and medicine.

86. Given the history of opioid use in the U.S. and the medical profession's resulting wariness, the commercial success of Defendants' prescription opioids would not have been possible without a fundamental shift in prescribers' perception of the risks and benefits of long-term opioid use.

87. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, surpassing the wealth of storied families like the Rockefellers, the Mellons, and the Busches.[19] Because of Purdue and, in particular,

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causing it to be responsible for a significant percent of the total amount of MME in circulation even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

[17] Barry Meier, Pain Killer: A "Wonder" Drug's Trail of Addiction and Death (Rodale 2003).

[18] *See e.g.*, Hank Sims, *Humboldt's Black-Market Pills and Heroin Could be Laced With a Super-Deadly Compound, DHHS Warns*, Lost Coast Outpost (Apr. 14, 2017, 11:28AM), https://lostcoastoutpost.com/2017/apr/14/humboldts-black-market-pills-and-heroin-could-be-l/; *Mislabeled painkillers "a fatal overdose waiting to happen,"* CBS News (Feb. 29, 2016, 10:46am), https://www.cbsnews.com/news/mislabeled-painkillers-a-fatal-overdose-waiting-to-happen/.

[19] Alex Morrell, *The OxyContin Clan: The $14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*, Forbes (July 1, 2015, 10:17am),

OxyContin, the Sacklers' net worth was $13 billion as of 2016. Today, all nine members of the Purdue board are family members, and all of the company's profits go to Sackler family trusts and entities.[20] Yet the Sacklers have avoided publicly associating themselves with Purdue, letting others serve as the spokespeople for the company.

88. The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small patent-medicine company called The Purdue Frederick Company in 1952. While all three brothers were accomplished psychiatrists, it was Arthur, the oldest, who directed the Sackler story, treating his brothers more as his protégés than colleagues, putting them both through medical school and essentially dictating their paths. It was Arthur who created the Sackler family's wealth, and it was Arthur who created the pharmaceutical advertising industry as we know it—laying the groundwork for the OxyContin promotion that would make the Sacklers billionaires.

89. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McAdams. Arthur pioneered both print advertising in medical journals and promotion through physician "education" in the form of seminars and continuing medical education courses. He understood intuitively the persuasive power of recommendations from fellow physicians, and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.[21]

90. It was Arthur who, in the 1960s, made Valium into the first $100-million drug, so popular it became known as "Mother's Little Helper." His expertise as a psychiatrist was key to

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https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#382ab3275e02.

[20] David Armstrong, *The man at the center of the secret OxyContin files*, Stat News (May 12, 2016), https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/.

[21] Meier, *supra* note 17, at 204.

his success; as his biography in the Medical Advertising Hall of Fame notes, it "enabled him to position different indications for Roche's Librium and Valium—to distinguish for the physician the complexities of anxiety and psychic tension."[22] When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution.[23] The campaign, for which Arthur was compensated based on volume of pills sold,[24] was a remarkable success.

91. Arthur's entrepreneurial drive led him to create not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which he distributed for free to doctors nationwide. Arthur also conceived a company now called IMS Health Holdings Inc., which monitors prescribing practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies like Defendants, who utilize it to tailor their sales pitches to individual physicians.

92. Even as he expanded his business dealings, Arthur was adept at hiding his involvement in them. When, during a 1962 Senate hearing about deceptive pharmaceutical advertising, he was asked about a public relations company called Medical and Science Communications Associates, which distributed marketing from drug companies disguised as news articles, Arthur was able to truthfully testify that he never was an officer for nor had any stock in that company. But the company's sole shareholder was his then-wife. Around the same time, Arthur also successfully evaded an investigative journalist's attempt to link the Sacklers to a company called MD Publications, which had funneled payments from drug companies to an FDA official named Henry Welch, who was forced to resign when the scandal broke.[25] Arthur

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[22] *MAHF Inductees, Arthur M. Sackler*, Med. Advert. Hall of Fame, https://www.mahf.com/mahf-inductees/ (last visited July 17, 2018).

[23] Meier, *supra* note 17, at 202; *One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids.

[24] WBUR On Point interview, *supra* note 23.

[25] Meier, *supra* note 17, at 210-14.

had set up such an opaque and layered business structure that his connection to MD Publications was only revealed decades later when his heirs were fighting over his estate.

93. Arthur Sackler did not hesitate to manipulate information to his advantage. His legacy is a corporate culture that prioritizes profits over people. In fact, in 2007, federal prosecutors conducting a criminal investigation of Purdue's fraudulent advertising of OxyContin found a "corporate culture that allowed this product to be misbranded with the intent to defraud and mislead."[26] Court documents from the prosecution state that "certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications . . . "[27] Half a century after Arthur Sackler wedded advertising and medicine, Purdue employees were following his playbook, putting product sales over patient safety.

3. Purdue and the development of OxyContin

94. After the Sackler brothers acquired The Purdue Frederick Company in 1952, Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running Purdue because that would have been a conflict of interest. Raymond Sackler became Purdue's head executive while Mortimer Sackler ran Purdue's UK affiliate.

95. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. Purdue marketed this extended-release morphine as MS Contin. It quickly became Purdue's best seller. As the patent expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time, Raymond Sackler's oldest son, Richard Sackler, who was also a trained physician, became more involved in the management of the company. Richard Sackler had grand ambitions for the

[26] Naomi Spencer, *OxyContin manufacturer reaches $600 million plea deal over false marketing practices*, World Socialist Web Site (May 19, 2007), http://www.wsws.org/en/articles/2007/05/oxy-m19.html.

[27] Agreed Statement of Facts, *United States. v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

company; according to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big."[28] Richard Sackler believed Purdue should develop another use for its "Contin" timed-release system.

96. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard Sackler and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen combination pill. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxy*codeine*," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this to its advantage when it eventually pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . . that would affect the unique position that OxyContin'" held among physicians.[29]

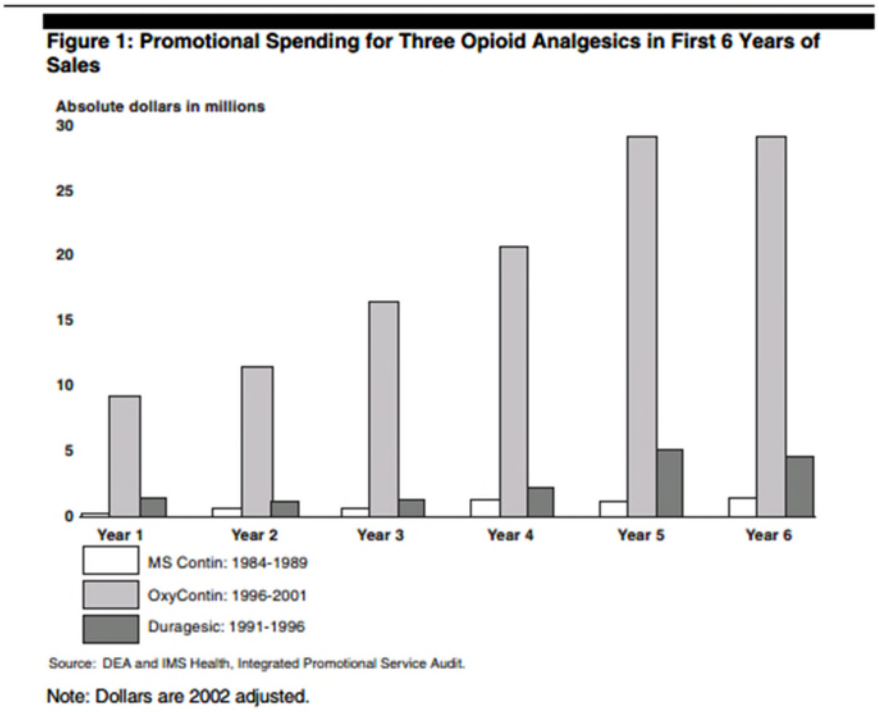
97. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk, and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase.[30] As discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue from making that claim regardless.

98. Despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market

[28] Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017), http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/.
[29] *United States. v. Purdue Frederick Co.*, *supra* note 27.
[30] Meier, *supra* note 17, at 269.

for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the Early Show, a CBS morning talk program, "There are 50 million patients in this country who have chronic pain that's not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that."[31]

99. In pursuit of these 50 million potential customers, Purdue poured resources into OxyContin's sales force and advertising. The graph below shows how promotional spending in the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or Defendant Janssen's spending on Duragesic:[32]



100. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners. Today, one in every five patients who present themselves to physicians' offices with non-cancer pain

[31] *Id.* at 156.

[32] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. Gen. Acct. Off. Rep. to Cong. Requesters at 22 (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid prescription.[33]

101. Purdue has generated estimated sales of more than $35 billion from opioids since 1996, while raking in more than $3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

102. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

103. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

> We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .
>
> Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated

[33] Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Ctrs. for Disease Control and Prevention (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm [hereinafter 2016 CDC Guideline].

> American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .
>
> In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.[34]

104. Purdue's pivot to untapped markets, after extracting substantial profits from communities like Humboldt County and leaving the County to address the resulting damage, underscores that its actions have been knowing, intentional, and motivated by profits throughout this entire tragic story.

B. The Booming Business of Addiction

1. Other Manufacturing Defendants leapt at the opioid opportunity.

105. Purdue created a market in which the prescription of powerful opioids for a range of common aches and pains was not only acceptable but encouraged—but it was not alone. Defendants Endo, Janssen, Cephalon, and Actavis, each of which already produced and sold prescription opioids, positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin while misrepresenting the safety and efficacy of their products.

106. Endo, which for decades had sold Percocet and Percodan, both containing relatively low doses of oxycodone, moved quickly to develop a generic version of extended-release oxycodone to compete with OxyContin, receiving tentative FDA approval for its generic version in 2002. As Endo stated in its 2003 Form 10-K, it was the first to file an application with the FDA for bioequivalent versions of the 10, 20, and 40 mg strengths of OxyContin, which

[34] Letter from Cong. of the U.S., to Dr. Margaret Chan, Dir.-Gen., World Health Org. (May 3, 2017), http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf.

potentially entitled it to 180 days of generic marketing exclusivity—"a significant advantage."[35] Purdue responded by suing Endo for patent infringement, litigating its claims through a full trial and a Federal Circuit appeal—unsuccessfully. As the trial court found, and the appellate court affirmed, Purdue obtained the oxycodone patents it was fighting to enforce through "inequitable conduct"—namely, suggesting that its patent applications were supported by clinical data when in fact they were based on an employee's "insight and not scientific proof."[36] Endo began selling its generic extended-release oxycodone in 2005.

107. At the same time as Endo was battling Purdue over generic OxyContin—and as the U.S. was battling increasingly widespread opioid abuse—Endo was working on getting another branded prescription opioid on the market. In 2002, Endo submitted applications to the FDA for both immediate-release and extended-release tablets of oxymorphone, branded as Opana and Opana ER.

108. Like oxycodone, oxymorphone is not a new drug; it was first synthesized in Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name Numorphan, in injectable, suppository, and oral tablet forms. But the oral tablets proved highly susceptible to abuse. Called "blues" after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin, and even had its moment in the limelight as the focus of the movie Drugstore Cowboy. As the National Institute on Drug Abuse observed in its 1974 report, "Drugs and Addict Lifestyle," Numorphan was extremely popular among addicts for its quick and sustained effect.[37] Endo withdrew oral Numorphan from the market in 1979, reportedly for "commercial reasons."[38]

109. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before

[35] *Endo Pharm. Holdings, Inc. Form 10-K*, U.S. Sec. and Exchange Comm'n, at 4 (Mar. 15, 2004), http://media.corporate-ir.net/media_files/irol/12/123046/reports/10K_123103.pdf.
[36] *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).
[37] John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015), https://www.medpagetoday.com/psychiatry/addictions/51448.
[38] *Id*.

Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and pushed it into the marketplace with a new trade name and a potent extended-release formulation.

110. The clinical trials submitted with Endo's first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone, an opioid antagonist that can reverse an overdose. Endo then submitted new "enriched enrollment" clinical trials, in which trial subjects who do not respond to the drug are excluded from the trial, and obtained approval. Endo began marketing Opana and Opana ER in 2006.

111. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that "the agency is seeking removal based on its concern that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse."[39] On July 6, 2017, Endo agreed to withdraw Opana ER from the market.[40]

112. Janssen, which already marketed the Duragesic (fentanyl) patch, developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

113. Cephalon also manufactures Actiq, a fentanyl lozenge, and Fentora, a fentanyl tablet. As noted above, fentanyl is an extremely powerful synthetic opioid. According to the DEA, as little as two milligrams is a lethal dosage for most people. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid

[39] Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse* (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.

[40] *Endo pulls opioid as U.S. seeks to tackle abuse epidemic*, Reuters (July 6, 2017, 9:59am), https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II.

therapy for the underlying persistent cancer pain."[41] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[42]

114. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

115. Actavis acquired the rights to Kadian, extended-release morphine, in 2008, and began marketing Kadian in 2009. Actavis's opioid products also include Norco, a brand-name hydrocodone and acetaminophen pill, first approved in 1997. But Actavis, primarily a generic drugmaker, pursued opioid profits through generics, selling generic versions of OxyContin, Opana, and Duragesic. In 2013, it settled a patent lawsuit with Purdue over its generic version of "abuse-deterrent" OxyContin, striking a deal that would allow it to market its abuse-deterrent oxycodone formulation beginning in 2014. Actavis anticipated over $100 million in gross profit from generic OxyContin sales in 2014 and 2015.

116. Mallinckrodt's generic oxycodone achieved enough market saturation to have its own street name, "M's," based on its imprint on the pills. As noted above, Mallinckrodt was the subject of a federal investigation based on diversion of its oxycodone in Florida, where 500 million of its pills were shipped between 2008 and 2012. Federal prosecutors alleged that 43,991 orders from distributors and retailers were excessive enough be considered suspicious and should have been reported to the DEA.

117. Mallinckrodt also pursued a share of the branded opioid market. In 2007, Mallinckrodt launched Magnacet, an oxycodone and acetaminophen combination pill. In 2008,

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[41] *Prescribing Information, ACTIQ®*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf (last visited July 17, 2018).

[42] *Prescribing Information, FENTORA®*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf (last visited July 17, 2018).

Mallinckrodt (then Covidien) launched TussiCaps, a hydrocodone and chlorpheniramine capsule, marketed as a cough suppressant. And in 2009, Mallinckrodt acquired the U.S. rights to Exalgo, a potent extended-release hydromorphone tablet, and began marketing it in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014. In anticipation of Xartemis XR's approval, Mallinckrodt hired approximately 200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."[43]

118. All told, the Manufacturing Defendants have reaped enormous profits from the addiction crisis they spawned. For example, Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013. Janssen earned more than $1 billion in sales of Duragesic in 2009, and Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

2. Distributor Defendants knowingly supplied dangerous quantities of opioids while advocating for limited oversight and enforcement.

119. The Distributor Defendants track and keep a variety of information about the pharmacies and other entities to which they sell pharmaceuticals. For example, the Distributor Defendants use "know your customer" questionnaires that track the number and types of pills their customers sell, absolute and relative amounts of controlled substances they sell, whether the customer purchases from other distributors, and types of medical providers in the areas, among other information.

120. These questionnaires and other sources of information available to the Distributor Defendants provide ample data to put the Distributor Defendants on notice of suspicious orders, pharmacies, and doctors.

121. Nevertheless, the Distributor Defendants refused or failed to identify, investigate, or report suspicious orders of opioids to the DEA. Even when the Distributor Defendants had

[43] Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Bus. Journal (Dec. 30, 2013), http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/.

actual knowledge that they were distributing opioids to drug diversion rings, they refused or failed to report these sales to the DEA.

122. By not reporting suspicious opioid orders or known diversions of prescription opioids, not only were the Defendants able to continue to sell opioids to questionable customers, Defendants ensured that the DEA had no basis for decreasing or refusing to increase production quotas for prescription opioids.

123. The Distributor Defendants collaborated with each other and with the Manufacturing Defendants to maintain distribution of excessive amounts of opioids. One example of this collaboration came to light through Defendants' work in support of legislation called the Ensuring Patient Access and Effective Drug Enforcement (EPAEDE) Act, which was signed into law in 2016 and limited the DEA's ability to stop the flow of opioids. Prior to this law, the DEA could use an "immediate suspension order" to halt suspicious shipments of pills that posed an "imminent" threat to the public. The EPAEDE Act changed the required showing to an "immediate" threat—an impossible standard given the fact that the drugs may sit on a shelf for a few days after shipment. The law effectively neutralized the DEA's ability to bring enforcement actions against distributors.

124. The legislation was drafted by a former DEA lawyer, D. Linden Barber, who is now a senior vice president at Defendant Cardinal Health. Prior to leaving the DEA, Barber had worked with Joseph Rannazzisi, then the chief of the DEA's Office of Diversion Control, to plan the DEA's fight against the diversion of prescription drugs. So when Barber began working for Cardinal Health, he knew just how to neutralize the effectiveness of the DEA's enforcement actions. Barber and other promoters of the EPAEDE Act portrayed the legislation as maintaining patient access to medication critical for pain relief. In a 2014 hearing on the bill, Barber testified about the "unintended consequences in the supply chain" of the DEA's enforcement actions. But by that time, communities across the United States, including Plaintiff Humboldt County, were grappling with the "unintended consequences" of Defendants' reckless promotion and distribution of narcotics.

125. Despite egregious examples of drug diversion from around the country, the promoters of the EPAEDE Act were successful in characterizing the bill as supporting patients' rights. One of the groups supporting this legislation was the Alliance for Patient Access, a "front group" as discussed further below, which purports to advocate for patients' rights to have access to medicines, and whose 2017 list of "associate members and financial supporters" included Defendants Purdue, Endo, Johnson & Johnson, Actavis, Mallinckrodt, and Cephalon. In a 2013 "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse," the Alliance for Patient Access asserted multiple "unintended consequences" of regulating pain medication, including a decline in prescriptions as physicians feel burdened by regulations and stigmatized.[44]

126. The Distributor Defendants are also part of the activities of the Alliance for Patient Access, although their involvement is hidden. One example of their involvement was revealed by the metadata of an electronic document: the letter from the Alliance for Patient Access in support of the EPAEDE Act. That document was created by Kristen Freitas, a registered lobbyist and the vice president for federal government affairs of the Healthcare Distributors Alliance (HDA)—the trade group that represents Defendants McKesson, Cardinal Health, and AmerisourceBergen.

127. Upon information and belief, the collaboration on the EPAEDE Act is just one example of how the Manufacturing Defendants and the Distributor Defendants, through third-party "front groups" like the Alliance for Patient Access and trade organizations like HDA, worked together behind the scenes to ensure that the flow of dangerous narcotics into communities across the country would not be restricted, and Defendants collaborated in other ways that remain hidden from public view.

128. The Distributor Defendants have been the subject of numerous enforcement actions by the DEA. In 2008, for example, McKesson was fined $13.3 million and agreed to

[44] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Inst. for Patient Access (Oct. 2013), http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.

strengthen its controls by implementing a three-tiered system that would flag buyers who exceeded monthly thresholds for opioids. As the opioid crisis deepened, the DEA's Office of Diversion Control, led by Rannazzisi, stepped up enforcement, filing fifty-two immediate suspension orders against suppliers and pill mills in 2010 alone. Defendant Cardinal Health was fined $34 million by the DEA in 2013 for failing to report suspicious orders.

129. The Distributor Defendants were not simply passive transporters of opioids. They intentionally failed to report suspicious orders and actively pushed back against efforts to enforce the law and restrict the flow of opioids into communities like Humboldt County.

3. Pill mills and overprescribing doctors also placed their financial interests ahead of their patients' interests.

130. Prescription opioid manufacturers and distributors were not the only ones to recognize an economic opportunity. Around the country, including in Humboldt County, certain doctors or pain clinics ended up doing brisk business dispensing opioid prescriptions. As Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, observed, this business model meant doctors would "have a practice of patients who'll never miss an appointment and who pay in cash."[45]

131. Moreover, the Manufacturing Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when their in-person visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions. Eventually, the DEA's diversion unit raided the clinic, and prosecutors filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,

[45] Sam Quinones, Dreamland: The True Tale of America's Opiate Epidemic 314 (Bloomsbury Press 2015).

Wilson was Purdue's top-ranked sales representative.[46] In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."[47]

132. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]"[48] She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report."[49] Purdue waited until after the clinic was shut down in 2010 to inform the authorities. By that time, 1.1 million pills were diverted from Los Angeles to Everett, Washington, a city of around 100,000 people.[50]

133. Whenever examples of opioid diversion and abuse have drawn media attention, the Manufacturing Defendants have consistently blamed "bad actors." For example, in 2001, during a Congressional hearing, Purdue's attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was "fooled" by the "bad actor" doctor: "The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon

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[46] Meier, *supra* note 17, at 298-300.
[47] *Id.*
[48] Harriet Ryan et al., *More Than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, Los Angeles Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.
[49] *Id.*
[50] Harriet Ryan et al., *How Black-Market OxyContin Spurred a Town's Descent into Crime, Addiction and Heartbreak*, Los Angeles Times (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-everett/.

this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us."[51]

134. But given the closeness with which all Defendants monitored prescribing patterns, including through IMS Health data, it is highly improbable that they were "fooled." In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino's clinic and alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Rather, it appears Purdue and other Defendants used the IMS Health data to target pill mills and sell more pills. Indeed, a Purdue executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

135. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

4. Widespread prescription opioid use broadened the market for heroin and fentanyl.

136. Defendants' scheme achieved a dramatic expansion of the U.S. market for opioids, prescription and non-prescription alike. Heroin and fentanyl use has surged—a foreseeable consequence of Defendants' successful promotion of opioid use coupled with the sheer potency of their products.

137. In his book *Dreamland: The True Tale of America's Opiate Epidemic*, journalist Sam Quinones summarized the easy entrance of black tar heroin in a market primed by prescription opioids:

> His black tar, once it came to an area where OxyContin had already tenderized the terrain, sold not to tapped-out junkies but to younger kids, many from the suburbs, most of whom had money and all of whom were white. Their transition from Oxy to heroin, he saw, was a natural and easy one. Oxy addicts began by sucking on and dissolving the pills' timed-release coating. They were left with 40 or 80 mg of pure oxycodone. At first, addicts crushed the pills and snorted the powder. As their

[51] Meier, *supra* note 17, at 179.

> tolerance built, they used more. To get a bigger bang from the pill, they liquefied it and injected it. But their tolerance never stopped climbing. OxyContin sold on the street for a dollar a milligram and addicts very quickly were using well over 100 mg a day. As they reached their financial limits, many switched to heroin, since they were already shooting up Oxy and had lost any fear of the needle.[52]

138. In a study examining the relationship between the abuse of prescription opioids and heroin, researchers found that 75% of those who began their opioid abuse in the 2000s reported that their first opioid was a prescription drug.[53] As the graph below illustrates, prescription opioids replaced heroin as the first opioid of abuse beginning in the 1990s.

The JAMA Network

From: **The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years**

JAMA Psychiatry. 2014;71(7):821-826. doi:10.1001/jamapsychiatry.2014.366

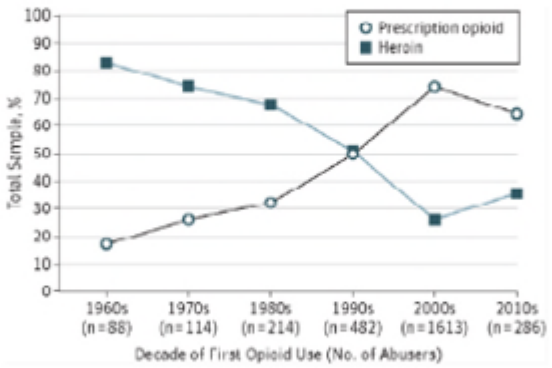

Figure Legend:

Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of AbuseData are plotted as a function of the decade in which respondents initiated their opioid abuse.

139. The researchers also found that nearly half of the respondents who indicated that their primary drug was heroin actually preferred prescription opioids, because the prescription drugs were legal, and perceived as "safer and cleaner." But, heroin's lower price point is a distinct advantage. While an 80 mg OxyContin might cost $80 on the street, the same high can

[52] Quinones, *supra* note 45, at 165-66.

[53] Theodore J. Cicero, PhD, Matthew S. Ellis, MPE, Hilary L. Surratt, PhD, *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71(7) JAMA Psychiatry 821-826 (2014), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.

be had from $20 worth of heroin.

140. As noted above, there is little difference between the chemical structures of heroin and prescription opioids. Between 2005 and 2009, Mexican heroin production increased by over 600%. And between 2010 and 2014, the amount of heroin seized at the U.S.-Mexico border more than doubled.

141. From 2002 to 2016, fatal overdoses related to heroin in the U.S. increased by **533%**—from 2,089 deaths in 2002 to 13,219 deaths in 2016.[54]

142. Along with heroin use, illicitly manufactured fentanyl use is on the rise, as a result of America's expanded appetite for opioids. But fentanyl, as noted above, is fifty times more potent than heroin, and overdosing is all too easy. Fentanyl is expected to cause over 20,000 overdoses in 2017.[55]

143. As Dr. Caleb Banta-Green, senior research scientist at the University of Washington's Alcohol and Drug Abuse Institute, observed in 2017, "The bottom line is opioid addiction is the overall driver of deaths. People will use whatever opioid they can get. It's just that which one they're buying is changing a bit."[56]

144. In addition to the expanded market for opioids of all kinds, the opioid epidemic has contributed to a resurgence in methamphetamine use, as some opioid users turn to the stimulant to counter the effects of opioids.[57] As explained in a recent article regarding the

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[54] Niall McCarthy, *U.S. Heroin Deaths Have Increased 533% Since 2002*, Forbes (Sept. 11, 2017, 8:26am), https://www.forbes.com/sites/niallmccarthy/2017/09/11/u-s-heroin-deaths-have-increased-533-since-2002-infographic/#13ab9a531abc.

[55] *Id.*

[56] *Opioids: The Leading Cause of Drug Deaths in Seattle Area*, U. of Wash. Sch. of Pub. Health (Aug. 25, 2017), http://sph.washington.edu/news/article.asp?content_ID=8595.

[57] *See, e.g.*, *Opioids and methamphetamine: a tale of two crises*, 391(10122) The Lancet 713 (Feb. 24, 2018), https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)30319-2/fulltext; Brenda Goodman, MA, *Experts Warn of Emerging 'Stimulant Epidemic'*, WebMD (Apr. 3, 2018). https://www.webmd.com/mental-health/addiction/news/20180403/experts-warn-of-emerging-stimulant-epidemic.

connection between opioids and methamphetamine, "[f]or addicts, the drugs pair: Heroin is a downer and methamphetamine is an upper."[58]

C. The Manufacturing Defendants Promoted Prescription Opioids Through Several Channels.

145. Despite knowing the devastating consequences of widespread opioid use, the Manufacturing Defendants engaged in a sophisticated and multi-pronged promotional campaign designed to achieve just that. By implementing the strategies pioneered by Arthur Sackler, these Defendants were able to achieve the fundamental shift in the perception of opioids that was key to making them blockbuster drugs.

146. The Manufacturing Defendants disseminated their deceptive statements about opioids through several channels.[59] First, these Defendants aggressively and persistently pushed opioids through sales representatives. Second, these Defendants funded third-party organizations that appeared to be neutral but which served as additional marketing departments for drug companies. Third, these Defendants utilized prominent physicians as paid spokespeople—"Key Opinion Leaders"—to take advantage of doctors' respect for and reliance on the recommendations of their peers. Finally, these Defendants also used print and online advertising, including unbranded advertising, which is not reviewed by the FDA.

147. The Manufacturing Defendants spent substantial sums and resources in making these communications. For example, Purdue spent more than $200 million marketing OxyContin in 2001 alone.[60]

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[58] Michelle Theriault Boots, *The silent fallout of the opioid epidemic? Meth.*, Anchorage Daily News (Mar. 29, 2018), https://www.adn.com/alaska-news/2018/03/19/the-silent-fallout-of-the-opioid-epidemic-meth/#_.

[59] The specific misrepresentations and omissions are discussed below in Section D.

[60] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of Paul Goldenheim, Vice President for Research, Purdue Pharma), https://www.gpo.gov/fdsys/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm.

1. The Manufacturing Defendants aggressively deployed sales representatives to push their products.

148. The Manufacturing Defendants communicated to prescribers directly in the form of in-person visits and communications from sales representatives.

149. The Manufacturing Defendants' tactics through their sales representatives—also known as "detailers"—were particularly aggressive. In 2014, Manufacturing Defendants collectively spent well over $100 million on detailing branded opioids to doctors.

150. Each sales representative has a specific sales territory and is responsible for developing a list of about 105 to 140 physicians to call on who already prescribe opioids or who are candidates for prescribing opioids.

151. When Purdue launched OxyContin in 1996, its 300-plus sales force had a total physician call list of approximately 33,400 to 44,500. By 2000, nearly 700 representatives had a total call list of approximately 70,500 to 94,000 physicians. Each sales representative was expected to make about thirty-five physician visits per week and typically called on each physician every three to four weeks, while each hospital sales representative was expected to make about fifty physician visits per week and call on each facility every four weeks.[61]

152. One of Purdue's early training memos compared doctor visits to "firing at a target," declaring that "[a]s you prepare to fire your 'message,' you need to know where to aim and what you want to hit!"[62] According to the memo, the target is physician resistance based on concern about addiction: "The physician wants pain relief for these patients without addicting them to an opioid."[63]

153. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist that the most common objection he heard about prescribing OxyContin was that "it's just too addictive."[64] In order to overcome that objection and hit their

[61] *OxyContin Abuse and Diversion and Efforts to Address the Problem, supra* note 32, at 20.
[62] Meier, *supra* note 17, at 102.
[63] *Id.*
[64] David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe), New Yorker (Oct. 27, 2017), https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses.

"target," May and other sales representatives were taught to say, "The delivery system is believed to reduce the abuse liability of the drug."[65] May repeated that line to doctors even though he "found out pretty fast that it wasn't true."[66] He and his coworkers learned quickly that people were figuring out how to remove the time-releasing coating, but they continued making this misrepresentation until Purdue was forced to remove it from the drug's label.

154. Purdue trained its sales representatives to misrepresent the addiction risk in other ways. May explained that he and his coworkers were trained to "refocus" doctors on "legitimate" pain patients, and to represent that "legitimate" patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less "habit-forming" than painkillers that need to be taken every four hours. Similarly, former Purdue sales manager William Gergely told a Florida state investigator in 2002 that sales representatives were instructed to say that OxyContin was "virtually non-addicting" and "non-habit-forming."[67]

155. As Shelby Sherman, a Purdue sales representative from 1974 to 1998, told a reporter regarding OxyContin promotion, "It was sell, sell, sell. We were directed to lie. Why mince words about it?"[68]

156. The Manufacturing Defendants utilized lucrative bonus systems to encourage their sales representatives to stick to the script and increase opioid sales in their territories. Purdue paid $40 million in sales incentive bonuses to its sales representatives in 2001 alone, with annual bonuses ranging from $15,000 to nearly $240,000.[69] The training memo described above,

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[65] Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain; see also Meier, *supra* note 17, at 102 ("Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of the drug.").

[66] Keefe, *supra* note 65.

[67] Fred Schulte and Nancy McVicar, *Oxycontin Was Touted As Virtually Nonaddictive, Newly Released State Records Show*, Sun Sentinel (Mar. 6, 2003), http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely.

[68] Glazek, *supra* note 28.

[69] Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health 221-27 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.

in keeping with a Wizard of Oz theme, reminded sales representatives: "A pot of gold awaits you 'Over the Rainbow'!"[70]

157. As noted above, these Defendants have also spent substantial sums to purchase, manipulate, and analyze prescription data available from IMS Health, which allows them to track initial prescribing and refill practices by individual doctors, and in turn to customize their communications with each doctor. The Manufacturing Defendants' use of this marketing data was a cornerstone of their marketing plan,[71] and continues to this day.

158. The Manufacturing Defendants also aggressively pursued family doctors and primary care physicians perceived to be susceptible to their marketing campaigns. The Manufacturing Defendants knew that these doctors relied on information provided by pharmaceutical companies when prescribing opioids, and that, as general practice doctors seeing a high volume of patients on a daily basis, they would be less likely to scrutinize the companies' claims.

159. Furthermore, the Manufacturing Defendants knew or should have known the doctors they targeted were often poorly equipped to treat or manage pain comprehensively, as they often had limited resources or time to address behavioral or cognitive aspects of pain treatment or to conduct the necessary research themselves to determine whether opioids were as beneficial as these Defendants claimed. In fact, the majority of doctors and dentists who prescribe opioids are not pain specialists. For example, a 2014 study conducted by pharmacy benefit manager Express Scripts reviewing narcotic prescription data from 2011 to 2012 concluded that of the more than 500,000 prescribers of opioids during that time period, *only 385* were identified as pain specialists.[72]

160. When the Manufacturing Defendants presented these doctors with sophisticated marketing material and apparently scientific articles that touted opioids' ability to easily and

[70] Meier, *supra* note 17, at 103.
[71] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 69.
[72] *A Nation in Pain*, Express Scripts (Dec. 9, 2014), http://lab.express-scripts.com/lab/publications/a-nation-in-pain.

safely treat pain, many of these doctors began to view opioids as an efficient and effective way to treat their patients.

161. In addition, sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative in Florida wrote about working for a particularly driven regional manager named Chris Sposato and described how Sposato would drill the sales team on their upselling tactics:

> It went something like this. "Doctor, what is the highest dose of OxyContin you have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?" "Okay." "Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?" "I don't know, maybe." "Doctor, but you do agree that you would at least Rx the 40mg dose, right?" "Yes."
>
> The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Miami District reps have told me that on work sessions with [Sposato] they would sit in the car and role play for as long as it took until [Sposato] was convinced the rep was delivering the message with perfection.

162. The Manufacturing Defendants used not only incentives but competitive pressure to push sales representatives into increasingly aggressive promotion. One Purdue sales representative recalled the following scene: "I remember sitting at a round table with others from my district in a regional meeting while everyone would stand up and state the highest dose that they had suckered a doctor to prescribe. The entire region!!"

163. Sales representatives also quickly learned that the prescription opioids they were promoting were dangerous. For example, May had only been at Purdue for two months when he found out that a doctor he was calling on had just lost a family member to an OxyContin overdose.[73] And as another sales representative wrote on a public forum:

> Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid picks out a green pill from the bowl... they go to sleep and don't wake up (because

[73] Remnick, *supra* note 64.

they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

164. The Manufacturing Defendants' sales representatives also provided health care providers with pamphlets, visual aids, and other marketing materials designed to increase the rate of opioids prescribed to patients. These sales representatives knew the doctors they visited relied on the information they provided, and that the doctors had minimal time or resources to investigate the materials' veracity independently.

165. Sales representatives were also given bonuses when doctors whom they had detailed wrote prescriptions for their company's drug. Because of this incentive system, sales representatives stood to gain significant bonuses if they had a pill mill in their sales region. Sales representatives could be sure that doctors and nurses at pill mills would be particularly receptive to their messages and incentives, and receive "credit" for the many prescriptions these pill mills wrote.

166. The Manufacturing Defendants applied this combination of intense competitive pressure and lucrative financial incentives because they knew that sales representatives, with their frequent in-person visits with prescribers, were incredibly effective. In fact, manufacturers' internal documents reveal that they considered sales representatives their "most valuable resource."

2. The Manufacturing Defendants bankrolled seemingly independent "front groups" to promote opioid use and fight restrictions on opioids.

167. The Manufacturing Defendants funded, controlled, and operated third-party organizations that communicated to doctors, patients, and the public the benefits of opioids to treat chronic pain. These organizations—also known as "front groups"—appeared independent and unbiased. But in fact, they were but additional paid mouthpieces for the drug manufacturers. These front groups published prescribing guidelines and other materials that promoted opioid treatment as a way to address patients' chronic pain. The front groups targeted doctors, patients, and lawmakers, all in coordinated efforts to promote opioid prescriptions.

168. The Manufacturing Defendants spent significant financial resources contributing to and working with these various front groups to increase the number of opioid prescriptions written.

169. The most prominent front group utilized by the Manufacturing Defendants was the **American Pain Foundation** (APF), which received more than $10 million from opioid drug manufacturers, including Defendants, from 2007 through 2012. For example, Purdue contributed $1.7 million and Endo also contributed substantial sums to the APF.[74]

170. Throughout its existence, APF's operating budget was almost entirely comprised of contributions from prescription opioid manufacturers. For instance, nearly 90% of APF's $5 million annual budget in 2010 came from "donations" from some of the Manufacturing Defendants, and by 2011, APF was entirely dependent on grants from drug manufacturers, including from Purdue and Endo. Not only did Defendants control APF's purse strings, APF's board of directors was comprised of doctors who were on Defendants' payrolls, either as consultants or speakers at medical events.[75]

171. Although holding itself out as an independent advocacy group promoting patient well-being, APF consistently lobbied against federal and state proposals to limit opioid use.

172. Another prominent front group was the **American Academy of Pain Medicine** (AAPM), which has received over $2.2 million in funding since 2009 from opioid drug manufacturers, including Defendants. Like APF, AAPM presented itself as an independent and non-biased advocacy group representing physicians practicing in the field of pain medicine, but in fact was just another mouthpiece the Manufacturing Defendants used to push opioids on doctors and patients.[76]

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[74] Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15am), https://www.propublica.org/article/the-champion-of-painkillers.

[75] *Id*.

[76] Tracy Weber and Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 9:14am), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry.

173. Both the APF and the AAPM published treatment guidelines and sponsored and hosted medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks. The treatment guidelines the front groups published—many of which are discussed in detail below—were particularly important to Defendants in ensuring widespread acceptance for opioid therapy to treat chronic pain. Defendants realized, just as the CDC has, that such treatment guidelines can "change prescribing practices," because they appear to be unbiased sources of evidence-based information, even when they are in reality marketing materials.

174. For instance, the AAPM, in conjunction with the **American Pain Society** (APS), issued comprehensive guidelines in 2009 titled "Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain – Evidence Review" ("2009 Guidelines"). The 2009 Guidelines promoted opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence to support this statement. Unsurprisingly, the Manufacturing Defendants have widely referenced and promoted these guidelines, issued by front groups these Defendants funded and controlled. These 2009 Guidelines are still available online today.[77]

175. The **Alliance for Patient Access** (APA), discussed above, was established in 2006, along with the firm that runs it, Woodberry Associates LLC. The APA describes itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care," but its list of "Associate Members and Financial Supporters" contains thirty drug companies, including each of the Manufacturing Defendants named in this lawsuit. In addition, the APA's board members include doctors who have received hundreds of thousands of dollars in payments from drug companies. As discussed above, the APA has been a vocal critic of policies restricting the flow of opioids and has supported efforts to curtail the DEA's ability to stop suspicious orders of prescription drugs.

[77] *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, Am. Pain Soc'y, http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cncp.pdf (last visited July 17, 2018).

176. The "white paper" issued by the APA in 2013 also echoed a favorite narrative of the Manufacturing Defendants, the supposed distinction between "legitimate patients" on the one hand and "addicts" on the other, asserting that one "unintended consequence" of regulating pain medication would be that "[p]atients with legitimate medical needs feel stigmatized, treated like addicts."[78]

177. Another group utilized by the Manufacturing Defendants to encourage opioid prescribing practices, a University of Wisconsin-based organization known as the **Pain & Policy Studies Group**, received $2.5 million from pharmaceutical companies to promote opioid use and discourage the passing of regulations against opioid use in medical practice. The Pain & Policy Studies Group wields considerable influence over the nation's medical schools as well as within the medical field in general.[79] Purdue was the largest contributor to the Pain & Policy Studies Group, paying approximately $1.6 million between 1999 and 2010.[80]

178. The **Federation of State Medical Boards** (FSMB) of the United States is a national non-profit organization that represents the seventy-state medical and osteopathic boards of the United States and its territories and co-sponsors the United States Medical Licensing Examination. Beginning in 1997, FSMB developed model policy guidelines around the treatment of pain, including opioid use. The original initiative was funded by the Robert Wood Johnson Foundation, but subsequently AAPM, APS, the University of Wisconsin Pain & Policy Studies Group, and the American Society of Law, Medicine, & Ethics all made financial contributions to the project.

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[78] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, *supra* note 44.

[79] *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com, https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/ (last visited July 17, 2018).

[80] John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011), http://archive.jsonline.com/watchdog/watchdogreports/120331689.html.

179. FSMB's 2004 *Model Policy* encourages state medical boards "to evaluate their state pain policies, rules, and regulations to identify *any regulatory restrictions or barriers that may impede the effective use of opioids* to relieve pain."[81] (Emphasis added).

180. One of the most significant barriers to convincing doctors that opioids were safe to prescribe to their patients for long-term treatment of chronic pain was the fact that many of those patients would, in fact, become addicted to opioids. If patients began showing up at their doctors' offices with obvious signs of addiction, the doctors would, of course, become concerned and likely stop prescribing opioids. And, doctors might stop believing the Manufacturing Defendants' claims that addiction risk was low.

181. To overcome this hurdle, the Manufacturing Defendants promoted a concept called "pseudoaddiction." These Defendants told doctors that when their patients appeared to be addicted to opioids—for example, asking for more and higher doses of opioids, increasing doses themselves, or claiming to have lost prescriptions in order to get more opioids—this was not actual addiction. Rather, the Manufacturing Defendants told doctors what appeared to be classic signs of addiction were actually just signs of undertreated pain. The solution to this "pseudoaddiction": more opioids. Instead of warning doctors of the risk of addiction and helping patients to wean themselves off of powerful opioids and deal with their actual addiction, the Manufacturing Defendants pushed even more dangerous drugs onto patients.

182. The FSMB's *Model Policy* gave a scientific veneer to this fictional and overstated concept. The policy defines "pseudoaddiction" as "[t]he iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction" and states that these behaviors "resolve upon institution of effective analgesic therapy."[82]

183. In May 2012, Senate Finance Committee Chairman Max Baucus and senior Committee member Chuck Grassley initiated an investigation into the connections of the

[81] *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Fed'n of St. Med. Boards of the U.S., Inc. (May 2004), http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/model04.pdf.

[82] *Id.*

Manufacturing Defendants with medical groups and physicians who have advocated increased opioid use.[83] In addition to Purdue, Endo, and Janssen, the senators sent letters to APF, APS, AAPM, FSMB, the University of Wisconsin Pain & Policy Studies Group, the Joint Commission on Accreditation of Healthcare Organization, and the Center for Practical Bioethics, requesting from each "a detailed account of all payments/transfers received from corporations and any related corporate entities and individuals that develop, manufacture, produce, market, or promote the use of opioid-based drugs from 1997 to the present."[84]

184. On the same day as the senators' investigation began, APF announced that it would "cease to exist, effective immediately."[85]

3. "It was pseudoscience": the Manufacturing Defendants paid prominent physicians to promote their products.

185. The Manufacturing Defendants retained highly credentialed medical professionals to promote the purported benefits and minimal risks of opioids. Known as "Key Opinion Leaders" or "KOLs," these medical professionals were often integrally involved with the front groups described above. The Manufacturing Defendants paid these KOLs substantial amounts to present at Continuing Medical Education ("CME") seminars and conferences, and to serve on their advisory boards and on the boards of the various front groups.

186. The Manufacturing Defendants also identified doctors to serve as speakers or attend all-expense-paid trips to programs with speakers.[86] The Manufacturing Defendants used these trips and programs—many of them lavish affairs—to incentivize the use of opioids while downplaying their risks, bombarding doctors with messages about the safety and efficacy of

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[83] *Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups*, U.S. Senate Comm. on Fin. (May 8, 2012), https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups.

[84] Letter from U.S. Senate Comm. on Fin. to Am. Pain Found. (May 8, 2012), https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Foundation2.pdf.

[85] Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57pm), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups.

[86] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 69.

opioids for treating long-term pain. Although often couched in scientific certainty, the Manufacturing Defendants' messages were false and misleading, and helped to ensure that millions of Americans would be exposed to the profound risks of these drugs.

187. It is well documented that this type of pharmaceutical company symposium influences physicians' prescribing, even though physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.[87] For example, doctors who were invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.[88]

188. The KOLs gave the impression they were independent sources of unbiased information, while touting the benefits of opioids through their presentations, articles, and books. KOLs also served on committees and helped develop guidelines such as the 2009 Guidelines described above that strongly encouraged the use of opioids to treat chronic pain.

189. One of the most prominent KOLs for the Manufacturing Defendants' opioids was Dr. Russell Portenoy. A respected leader in the field of pain treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, described him "lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been studied.'"[89]

190. As one organizer of CME seminars, who worked with Portenoy and Purdue, pointed out, "had Portenoy not had Purdue's money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue's millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified."[90]

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[87] *Id.*

[88] Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — "We're only just getting started"*, Los Angeles Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/.

[89] Quinones, *supra* note 45, at 314.

[90] *Id.* at 136.

191. In recent years, some of the Manufacturing Defendants' KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature.[91] Dr. Portenoy himself specifically admitted that he overstated the drugs' benefits and glossed over their risks, and that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[92] He mused, "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did . . . We didn't know then what we know now."[93]

192. Dr. Portenoy did not need "the standards of 2012" to discern evidence-based science from baseless claims, however. When interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."[94]

193. Dr. Portenoy was perhaps the most prominent KOL for prescription opioids, but he was far from the only one. In fact, Dr. Portenoy and a doctor named Perry Fine co-wrote *A Clinical Guide to Opioid Analgesia*, which contained statements that conflict with the CDC's 2016 *Guideline for Prescribing Opioids for Chronic Pain*, such as the following examples regarding respiratory depression and addiction:

> At clinically appropriate doses, . . . respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.
>
> Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (ie, for

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[91] *See, e.g.*, John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012), http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/ (finding that a key Endo KOL acknowledged that opioid marketing went too far).

[92] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012, 11:36am), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

[93] *Id.*

[94] Meier, *supra* note 17, at 277.

> acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.[95]

194. Dr. Fine is a Professor of Anesthesiology at the University of Utah School of Medicine's Pain Research Center. He has served on Purdue's advisory board, provided medical legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.[96]

195. In 2011, he and Dr. Scott Fishman, discussed below, published a letter in *JAMA* called "Reducing Opioid Abuse and Diversion," which emphasized the importance of maintaining patient access to opioids.[97] The editors of *JAMA* found that both doctors had provided incomplete financial disclosures and made them submit corrections listing all of their ties to the prescription painkiller industry.[98]

196. Dr. Fine also failed to provide full disclosures as required by his employer, the University of Utah. For example, Dr. Fine told the university that he had received under $5,000 in 2010 from Johnson & Johnson for providing "educational" services, but Johnson & Johnson's website states that the company paid him $32,017 for consulting, promotional talks, meals and travel that year.[99]

197. In 2012, along with other KOLs, Dr. Fine was investigated for his ties to drug companies as part of the Senate investigation of front groups described above. When Marianne

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[95] Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill Companies (2004), http://www.thblack.com/links/RSD/OpioidHandbook.pdf.

[96] Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1445 (Sept. 20, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true.

[97] Perry G. Fine, MD and Scott M. Fishman, MD, *Reducing Opioid Abuse and Diversion*, 306 (4) JAMA 381 (July 27, 2011), https://jamanetwork.com/journals/jama/article-abstract/1104144?redirect=true.

[98] *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 (13) JAMA 1446 (Oct. 5, 2011), https://jamanetwork.com/journals/jama/fullarticle/1104453.

[99] Weber and Ornstein, *Two Leaders in Pain Treatment*, *supra* note 76.

Skolek, a reporter for the online news outlet Salem-News.com and a critic of opioid overuse, wrote an article about him and another KOL being investigated, Dr. Fine fired back, sending a letter to her editor accusing her of poor journalism and saying that she had lost whatever credibility she may have had. He criticized her for linking him to Purdue, writing, "I have never had anything to do with Oxycontin development, sales, marketing or promotion; I have never been a Purdue Pharma speaker"—neglecting to mention, of course, that he served on Purdue's advisory board, as the *JAMA* editors had previously forced him to disclose. [100]

198. Another Utah physician, Dr. Lynn Webster, was the director of Lifetree Clinical Research & Pain Clinic in Salt Lake City from 1990 to 2010, and in 2013 was the president of AAPM (one of the front groups discussed above). Dr. Webster developed a five-question survey he called the Opioid Risk Tool, which he asserted would "predict accurately which individuals may develop aberrant behaviors when prescribed opioids for chronic pain."[101] He published books titled *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of Us* and *Avoiding Opioid Abuse While Managing Pain*.

199. Dr. Webster and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the opioid industry's promotional messages, Dr. Webster apparently believed the solution to patients' tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills. Tina Webb, a Lifetree patient who overdosed in 2007, was taking as many as thirty-two pain pills a day in the year before she died, all while under doctor supervision.[102] Carol Ann Bosley, who sought treatment for pain at Lifetree after a serious car accident and multiple spine

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[100] Marianne Skolek, *Doctor Under Senate Investigation Lashes Out at Journalist*, Salem News (Aug. 12, 2012, 8:45pm), http://www.salem-news.com/articles/august122012/perry-fine-folo-ms.php.

[101] Lynn Webster and RM Webster, *Predicting aberrant behaviors in opioid-treated patients: preliminary validation of the Opioid Risk Tool* 6 (6) Pain Med. 432 (Nov.-Dec. 2005), https://www.ncbi.nlm.nih.gov/pubmed/16336480.

[102] Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national opioid epidemic*, Deseret News (Oct. 26, 2017, 12:01am), https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html.

surgeries, quickly became addicted to opioids and was prescribed increasing quantities of pills; at the time of her death, she was on seven different medications totaling approximately 600 pills a month.[103] Another woman, who sought treatment from Lifetree for chronic low back pain and headaches, died at age forty-two after Lifetree clinicians increased her prescriptions to fourteen different drugs, including multiple opioids, for a total of 1,158 pills a month.[104]

200. By these numbers, Lifetree resembles the pill mills and "bad actors" that the Manufacturing Defendants blame for opioid overuse. But Dr. Webster was an integral part of Defendants' marketing campaigns, a respected pain specialist who authored numerous CMEs sponsored by Endo and Purdue. And the Manufacturing Defendants promoted his Opioid Risk Tool and similar screening questionnaires as measures that allow powerful opioids to be prescribed for chronic pain.

201. Even in the face of patients' deaths, Dr. Webster continues to promote a pro-opioid agenda, even asserting that alternatives to opioids are risky because "[i]t's not hard to overdose on NSAIDs or acetaminophen."[105] He argued on his website in 2015 that DEA restrictions on the accessibility of hydrocodone harm patients, and in 2017 tweeted in response to CVS Caremark's announcement that it will limit opioid prescriptions that "CVS Caremark's new opioid policy is wrong, and it won't stop illegal drugs."[106]

202. Another prominent KOL is Dr. Scott M. Fishman, the Chief of the Department of Pain Medicine at University of California, Davis. He has served as president of APF and AAPM, and as a consultant and a speaker for Purdue, in addition to providing the company grant and research support. He also has had financial relationships with Endo and Janssen. He wrote a

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[103] Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN (Dec. 20, 2013, 7:06am), http://www.cnn.com/2013/12/20/health/pain-pillar/index.html.

[104] *Id*.

[105] *APF releases opioid medication safety module*, Drug Topics (May 10, 2011), http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/apf-releases-opioid-medication-safety-module.

[106] Lynn Webster, MD (@LynnRWebsterMD), Twitter (Dec. 7, 2017, 5:45pm), https://twitter.com/LynnRWebsterMD/status/938887130545360898.

book for the FSMB called *Responsible Opioid Use: A Physician's Guide*, which was distributed to over 165,000 physicians in the U.S.

203. When legislators in Washington state proposed legislation in 2010 to combat prescription opioid abuse, Dr. Fishman and Dr. Fine, along with Dr. Seddon Savage, published an editorial in the Seattle Times arguing that the legislation would harm patients, in particular by requiring chronic pain patients to consult with a pain specialist before receiving a prescription for a moderate to high dose of an opioid.[107]

204. These KOLs and others—respected specialists in pain medicine—proved to be highly effective spokespeople for the Manufacturing Defendants.

4. The Manufacturing Defendants used "unbranded" advertising as a platform for their misrepresentations about opioids.

205. The Manufacturing Defendants also aggressively promoted opioids through "unbranded advertising" to generally tout the benefits of opioids without specifically naming a particular brand-name opioid drug. Instead, unbranded advertising is usually framed as "disease awareness"—encouraging consumers to "talk to your doctor" about a certain health condition without promoting a specific product. A trick often used by pharmaceutical companies, unbranded advertising gives the pharmaceutical companies considerable leeway to make sweeping claims about health conditions or classes of drugs. In contrast, a "branded" advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as "fair balance." Branded advertising is also subject to FDA review for consistency with the drug's FDA-approved label.

206. Unbranded advertising allows pharmaceutical manufacturers to sidestep those requirements; "fair balance" and consistency with a drug's label are not required.

[107] Perry G. Fine, Scott M. Fishman, and Seddon R. Savage, *Bill to combat prescription abuse really will harm patients in pain*, Seattle Times (Mar. 16, 2010, 4:39pm), http://old.seattletimes.com/html/opinion/2011361572_guest17fine.html.

207. By engaging in unbranded advertising, the Manufacturing Defendants were and are able to avoid FDA review and issue general statements to the public including that opioids improve function, that addiction usually does not occur, and that withdrawal can easily be managed. The Manufacturing Defendants' unbranded advertisements either did not disclose the risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

208. Through the various marketing channels described above—all of which the Manufacturing Defendants controlled, funded, and facilitated, and for which they are legally responsible—these Defendants made false or misleading statements about opioids despite the lack of scientific evidence to support their claims, while omitting the true risk of addiction and death.

D. Specific Misrepresentations Made by the Manufacturing Defendants.

209. All the Manufacturing Defendants have made and/or continue to make false or misleading claims in the following areas: (1) the low risk of addiction to opioids, (2) opioids' efficacy for chronic pain and ability to improve patients' quality of life with long-term use, (3) the lack of risk associated with higher dosages of opioids, (4) the need to prescribe more opioids to treat withdrawal symptoms, and (5) that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids for chronic use. These illustrative but non-exhaustive categories of the Manufacturing Defendants' misrepresentations about opioids are described in detail below.

1. The Manufacturing Defendants falsely claimed that the risk of opioid abuse and addiction was low.

210. Collectively, the Manufacturing Defendants have made a series of false and misleading statements about the low risk of addiction to opioids over the past twenty years. The Manufacturing Defendants have also failed to take sufficient remedial measures to correct their false and misleading statements.

211. The Manufacturing Defendants knew that many physicians were hesitant to prescribe opioids other than for acute or cancer-related pain because of concerns about addiction.

Because of this general perception, sales messaging about the low risk of addiction was a fundamental prerequisite misrepresentation.

212. Purdue launched OxyContin in 1996 with the statement that OxyContin's patented continuous-release mechanism "is believed to reduce the abuse liability." This statement, which appeared in OxyContin's label and which sales representatives were taught to repeat verbatim, was unsupported by any studies, and was patently false. The continuous-release mechanism was simple to override, and the drug correspondingly easy to abuse. This fact was known, or should have been known, to Purdue prior to its launch of OxyContin, because people had been circumventing the same continuous-release mechanism for years with MS Contin, which in fact commanded a high street price because of the dose of pure narcotic it delivered. In addition, with respect to OxyContin, Purdue researchers notified company executives, including Raymond and Richard Sackler, by email that patients in their clinical trials were abusing the drug despite the timed-release mechanism.[108]

213. In 2007, as noted above, Purdue pleaded guilty to misbranding a drug, a felony under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a)(2). As part of its guilty plea, Purdue agreed that certain Purdue supervisors and employees had, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications" in the following ways:

> Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;
>
> Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

[108] WBUR On Point interview, *supra* note 23.

> Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
>
> Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[109]

214. All of these statements were false and misleading. But Purdue had not stopped there. Purdue—and later the other Defendants—manipulated scientific research and utilized respected physicians as paid spokespeople to convey its misrepresentations about low addiction risk in much more subtle and pervasive ways, so that the idea that opioids used for chronic pain posed a low addiction risk became so widely accepted in the medical community that Defendants were able to continue selling prescription opioids for chronic pain—even after Purdue's criminal prosecution.

215. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this "research" in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

216. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction "rare" for patients treated with opioids.[110] They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions or provided opioids to administer to

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[109] *United States v. Purdue Frederick Co.*, *supra* note 27; see also, Plea Agreement, *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

[110] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

themselves at home, nor was it known how frequently or infrequently and in what doses the patients were given their narcotics. Rather, it appears the patients were treated with opioids for short periods of time under in-hospital doctor supervision.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,[2] Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

217. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study, and that one could not conclude anything about long-term use of opioids from his figures.[111] Dr. Jick also recalled that no one from drug companies or patient advocacy groups contacted him for more information about the data.[112]

218. Nonetheless, the Manufacturing Defendants regularly invoked this letter as proof of the low addiction risk in connection with taking opioids despite its obvious shortcomings. These Defendants' egregious misrepresentations based on this letter included claims that *less than one percent* of opioid users become addicted.

219. The limited facts of the study did not deter the Manufacturing Defendants from using it as definitive proof of opioids' safety. The enormous impact of the Manufacturing Defendants' misleading amplification of this letter was well documented in another letter

[111] Meier, *supra* note 17, at 174.
[112] *Id.*

published in NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and in some cases "grossly misrepresented." In particular, the authors of this letter explained:

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy . . .[113]

220. Unfortunately, by the time of this analysis and the CDC's findings in 2016, the damage had already been done. "It's difficult to overstate the role of this letter," said Dr. David Juurlink of the University of Toronto, who led the analysis. "It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern."[114]

221. The Manufacturing Defendants successfully manipulated the 1980 Porter and Jick letter as the "evidence" supporting their fundamental misrepresentation that the risk of opioid addiction was low when opioids were prescribed to treat pain. For example, in its 1996 press release announcing the release of OxyContin, Purdue advertised that the "fear of addiction is exaggerated" and quoted the chairman of the American Pain Society Quality of Care Committee, who claimed that "there is very little risk of addiction from the proper uses of these [opioid] drugs for pain relief."[115]

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[113] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

[114] *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT News (May 31, 2017), https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/.

[115] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm), http://documents.latimes.com/oxycontin-press-release-1996/.

PR Newswire

May 31, 1996, Friday - 15:47 Eastern Time

NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM PERSISTENT

The fear of addiction is exaggerated.

One cause of patient resistance to appropriate pain treatment -- the fear of addiction -- is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief."

Paul D. Goldenheim, M.D., Vice President of Purdue Pharma L.P. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

222. Dr. Portenoy, the Purdue KOL mentioned previously, also stated in a promotional video from the 1990s that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[116]

223. Purdue also specifically used the Porter and Jick letter in its 1998 promotional video, "I got my life back," in which Dr. Alan Spanos says, "In fact, the rate of addiction amongst pain patients who are treated by doctors is *much less than 1%*."[117]

[116] Catan and Perez, *supra* note 92.

[117] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited July 17, 2018) (emphasis added).

224. The Porter and Jick letter was also used on Purdue's "Partners Against Pain" website, which was available in the early 2000s, where Purdue claimed that the addiction risk with OxyContin was very low.[118]

225. The Porter and Jick letter was used frequently in literature given to prescribing physicians and to patients who were prescribed OxyContin.[119]

226. In addition to the Porter and Jick letter, the Manufacturing Defendants exaggerated the significance of a study published in 1986 regarding cancer patients treated with opioids. Conducted by Dr. Portenoy and another pain specialist, Dr. Kathleen Foley, the study involved only 38 patients, who were treated for non-malignant cancer pain with low doses of opioids (the majority were given less than 20 MME/day, the equivalent of only 13 mg of oxycodone). [120] Of these thirty-eight patients, only two developed problems with opioid abuse, and Dr. Portenoy and Dr. Foley concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[121] Notwithstanding the small

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[118] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 69.

[119] Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing* (Aug. 22, 2001), https://web.archive.org/web/20170212210143/https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf.

[120] Russell K. Portenoy and Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 Pain 171-86 (1986), https://www.ncbi.nlm.nih.gov/pubmed/2873550.

[121] *Id.*

sample size, low doses of opioids involved, and the fact that all the patients were cancer patients, the Manufacturing Defendants used this study as "evidence" that high doses of opioids were safe for the treatment of chronic non-cancer pain.

227. The Manufacturing Defendants' repeated misrepresentations about the low risk of opioid addiction were so effective that this concept became part of the conventional wisdom. Dr. Nathaniel Katz, a pain specialist, recalls learning in medical school that previous fears about addiction were misguided, and that doctors should feel free to allow their patients the pain relief that opioids can provide. He did not question this until one of his patients died from an overdose. Then, he searched the medical literature for evidence of the safety and efficacy of opioid treatment for chronic pain. "There's not a shred of research on the issue. All these so-called experts in pain are dedicated and have been training me that opioids aren't as addictive as we thought. But what is that based on? It was based on nothing."[122]

228. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue continued to emphasize "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[123]

229. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question, "Aren't opioid pain medications like OxyContin Tablets 'addicting'? Even my family is concerned about this," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

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[122] Quinones, *supra* note 45, at 188-89.

[123] Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

230. Similarly, Dr. David Haddox, Senior Medical Director for Purdue, cavalierly stated, "[w]hen this medicine is used appropriately to treat pain under a doctor's care, it is not only effective, it is safe."[124] He went so far as to compare OxyContin to celery, because even celery would be harmful if injected: "If I gave you a stalk of celery and you ate that, it would be healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[125]

231. Purdue sales representatives also repeated these misstatements regarding the low risk for addiction to doctors across the country.[126] Its sales representatives targeted primary care physicians in particular, downplaying the risk of addiction and, as one doctor observed, "promot[ing] among primary care physicians a more liberal use of opioids."[127]

232. Purdue sales representatives were instructed to "distinguish between iatrogenic addiction (<1% of patients) and substance abusers/diversion (about 10% of the population abuse something: weed; cocaine; heroin; alcohol; valium; etc.)."[128]

233. Purdue also marketed OxyContin for a wide variety of conditions and to doctors who were not adequately trained in pain management.[129]

234. As of 2003, Purdue's Patient Information guide for OxyContin contained the following language regarding addiction:

> Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of addiction to opioid analgesics in properly managed patients with pain has been reported to be rare. However, data are not available to establish the true incidence of addiction in chronic pain patients.

235. Although Purdue has acknowledged it has made some misrepresentations about

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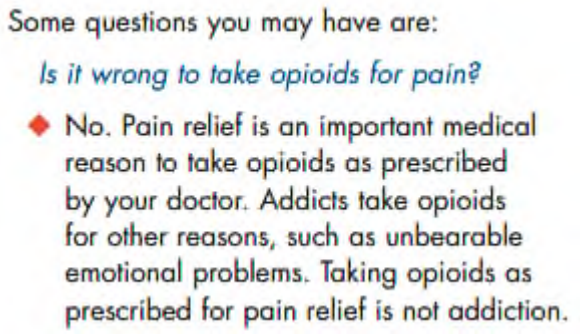
[124] Roger Alford, Deadly OxyContin abuse expected to spread in the U.S., Charleston Gazette, Feb. 9, 2001.
[125] *Id.*
[126] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, New York Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.
[127] Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 69.
[128] Meier, *supra* note 17, at 269.
[129] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 32.

the safety of its opioids,[130] it has done nothing to address the ongoing harms of their misrepresentations; in fact, it continues to make those misrepresentations today.

236. Defendant Endo also made dubious claims about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[131] The website has since been taken down.

237. In another website, PainAction.com—which is still currently available today—Endo also claimed that "most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[132]

238. In a pamphlet titled "Understanding Your Pain: Taking Oral Opioid Analgesics," Endo assured patients that addiction is something that happens to people who take opioids for reasons other than pain relief, "such as unbearable emotional problems"[133]:


Some questions you may have are:

Is it wrong to take opioids for pain?

- No. Pain relief is an important medical reason to take opioids as prescribed by your doctor. Addicts take opioids for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.

[130] Following the conviction in 2007 of three of its executives for misbranding OxyContin, Purdue released a statement in which they acknowledged their false statements. "Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information."

[131] German Lopez, *The growing number of lawsuits against opioid companies, explained*, Vox (Feb. 27, 2018, 2:25pm), https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits.

[132] *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), https://www.painaction.com/opioid-medication-addiction/.

[133] *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharms. (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

How can I be sure I'm not addicted?

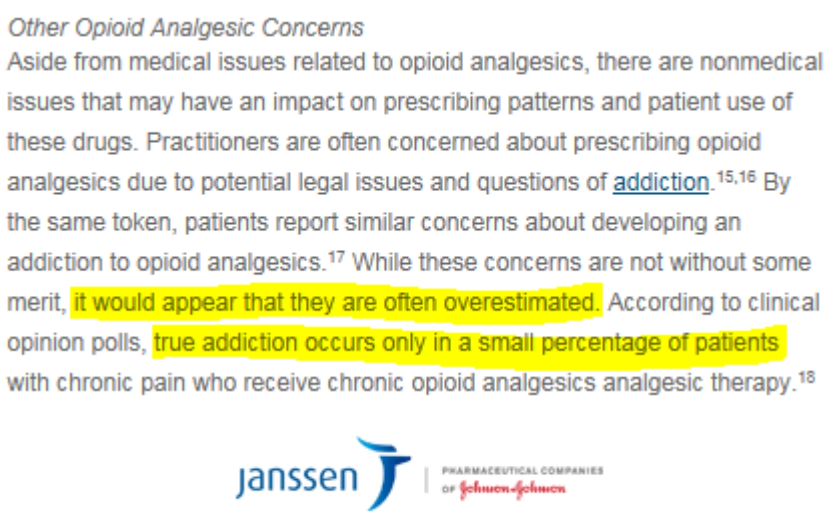
- Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
- Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve your pain and improve your function. You are not addicted.

239. In addition, Endo made statements in pamphlets and publications that most health care providers who treat people with pain agree that most people do not develop an addiction problem. These statements also appeared on websites sponsored by Endo, such as Opana.com.

240. In its currently active website, PrescribeResponsibly.com, Defendant Janssen states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[134]

Use of Opioid Analgesics in Pain Management

[134] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).



Other Opioid Analgesic Concerns

Aside from medical issues related to opioid analgesics, there are nonmedical issues that may have an impact on prescribing patterns and patient use of these drugs. Practitioners are often concerned about prescribing opioid analgesics due to potential legal issues and questions of addiction.[15,16] By the same token, patients report similar concerns about developing an addiction to opioid analgesics.[17] While these concerns are not without some merit, it would appear that they are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid analgesics analgesic therapy.[18]

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241. Similarly, in a 2009 patient education video titled "Finding Relief: Pain Management for Older Adults," Janssen sponsored a video by the American Academy of Pain Medicine that indicated that opioids are rarely addictive. The video has since been taken down.[135]

242. Janssen also approved and distributed a patient education guide in 2009 that attempted to counter the "myth" that opioids are addictive, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[136]

243. In addition, all the Manufacturing Defendants used third parties and front groups to further their false and misleading statements about the safety of opioids.

244. For example, in testimony for the Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the organization which, as described above, received the majority of its funding from opioid manufacturers, including Purdue, stated that "opioids are safe and effective, and only in rare

[135] Molly Huff, *Finding Relief: Pain Management for Older Adults*, Ctrs. for Pain Mgmt. (Mar. 9, 2011), http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults.

[136] Lopez, *supra* note 131.

cases lead to addiction."[137] Along with Dr. Giglio's testimony, the APF submitted a short background sheet on "the scope of the undertreatment of pain in the U.S.," which asserted that "opioids are often the best" treatment for pain that hasn't responded to other techniques, but that patients and many doctors "lack even basic knowledge about these options and fear that powerful pain drugs will [c]ause addiction." According to the APF, "most studies show that less than 1% of patients become addicted, which is medically different from becoming physically dependent."[138]

245. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio appeals court in December 2002, in which it claimed that "medical leaders have come to understand that the small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients."[139]

246. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," APF downplayed the risk of addiction and argued that concern about this risk should not prevent people from taking opioids: "Restricting access to the most effective medications for treating pain is not the solution to drug abuse or addiction."[140] APF also tried to normalize the dangers of opioids by listing opioids as one of several "[c]ommon drugs that can cause physical dependence," including steroids, certain heart medications, and caffeine.[141]

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[137] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), https://www.help.senate.gov/imo/media/doc/Giglio.pdf.

[138] *Id.*

[139] Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P.*, Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf.

[140] *Treatment Options: A Guide for People Living with Pain*, Am. Pain Found., https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited July 17, 2018).

[141] *Id.*

247. The Manufacturing Defendants' repeated statements about the low risk of addiction when taking opioids as prescribed for chronic pain were blatantly false and were made with reckless disregard for the potential consequences.

2. The Manufacturing Defendants falsely claimed that opioids were proven effective for chronic pain and would improve quality of life.

248. Not only did the Manufacturing Defendants falsely claim that the risk of addiction to prescription opioids was low, these Defendants represented that there was a significant upside to long-term opioid use, including that opioids could restore function and improve quality of life.[142]

249. Such claims were viewed as a critical part of the Manufacturing Defendants' marketing strategies. For example, an internal Purdue report from 2001 noted the lack of data supporting improvement in quality of life with OxyContin treatment:

> Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained release morphine . . . We do not have such data to support OxyContin promotion. . . . In addition, Janssen has been using the "life uninterrupted" message in promotion of Duragesic for non-cancer pain, stressing that Duragesic "helps patients think less about their pain." This is a competitive advantage based on our inability to make any quality of life claims.[143]

250. Despite the lack of data supporting improvement in quality of life, Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association in 2002, proclaiming, "There Can Be Life With Relief," and showing a man happily fly-fishing alongside his grandson.[144] This ad earned a warning letter from the FDA, which admonished, "It is particularly disturbing that your November ad would tout 'Life With Relief' yet fail to warn that patients can die from taking OxyContin."[145]

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[142] This case *does not* request or require the Court to specifically adjudicate whether opioids are appropriate for the treatment of chronic, non-cancer pain—though the scientific evidence strongly suggests they are not.

[143] Meier, *supra* note 17, at 281.

[144] *Id.* at 280.

[145] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall Street Journal (Jan. 23, 2003, 12:01am), https://www.wsj.com/articles/SB1043259665976915824.

251. Purdue also consistently tried to steer any concern away from addiction and focus on its false claims that opioids were effective and safe for treating chronic pain. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice President and Chief Operating Officer of Purdue, testified that "even the most vocal critics of opioid therapy concede the value of OxyContin in the legitimate treatment of pain," and that "OxyContin has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their ability to enjoy life."[146]

252. Purdue sponsored the development and distribution of an APF guide in 2011 which claimed that "multiple clinical studies have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." This guide is still available today.

253. Purdue also ran a series of advertisements of OxyContin in 2012 in medical journals titled "Pain vignettes," which were styled as case studies of patients with persistent pain conditions and for whom OxyContin was recommended to improve their function.

254. Purdue and Endo also sponsored and distributed a book in 2007 to promote the claim that pain relief from opioids, by itself, improved patients' function. The book remains for sale online today.

255. Endo's advertisements for Opana ER claimed that use of the drug for chronic pain allowed patients to perform demanding tasks like construction and portrayed Opana ER users as healthy and unimpaired.

256. Endo's National Initiative on Pain Control (NIPC) website also claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

[146] *Oxycontin: Its Use and Abuse*, *supra* note 123.

257. Endo further sponsored a series of CME programs through NIPC which claimed that chronic opioid therapy has been "shown to reduce pain and depressive symptoms and cognitive functioning."

258. Through PainKnowledge.org, Endo also supported and sponsored guidelines that stated, among other things, that "Opioid Medications are a powerful and often highly effective tool in treating pain," and that "they can help restore comfort, function, and quality of life."[147]

259. In addition, Janssen sponsored and edited patient guides which stated that "opioids may make it easier for people to live normally." The guides listed expected functional improvements from opioid use, including sleeping through the night, and returning to work, recreation, sex, walking, and climbing stairs.

260. Janssen also sponsored, funded, and edited a website which featured an interview edited by Janssen that described how opioids allowed a patient to "continue to function." This video is still available today.

261. Furthermore, sales representatives for the Manufacturing Defendants communicated and continue to communicate the message that opioids will improve patients' function, without appropriate disclaimers.

262. The Manufacturing Defendants' statements regarding opioids' ability to improve function and quality of life are false and misleading. As the CDC's *Guideline for Prescribing Opioids for Chronic Pain* (the "2016 CDC Guideline" or "Guideline")[148] confirms, not a single study supports these claims.

263. In fact, to date, there have been no long-term studies that demonstrate that opioids are effective for treating long-term or chronic pain. Instead, reliable sources of information, including from the CDC in 2016, indicate that there is "*[n]o evidence*" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain."[149] By contrast,

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[147] *Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007), https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf.

[148] 2016 CDC Guideline, *supra* note 33.

[149] *Id.*

significant research has demonstrated the colossal dangers of opioids. The CDC, for example, concluded that "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[150]

3. The Manufacturing Defendants falsely claimed doctors and patients could increase opioid usage indefinitely without added risk.

264. The Manufacturing Defendants also made false and misleading statements claiming that there is no dosage ceiling for opioid treatment. These misrepresentations were integral to the Manufacturing Defendants' promotion of prescription opioids for two reasons. First, the idea that there was no upward limit was necessary for the overarching deception that opioids are appropriate treatment for chronic pain. As discussed above, people develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose. Second, the dosing misrepresentation was necessary for the claim that OxyContin and competitor drugs allowed 12-hour dosing.

265. Twelve-hour dosing is a significant marketing advantage for any medication, because patient compliance is improved when a medication only needs to be taken twice a day. For prescription painkillers, the 12-hour dosing is even more significant because shorter-acting painkillers did not allow patients to get a full night's sleep before the medication wore off. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."[151]

266. Purdue executives therefore maintained the messaging of 12-hour dosing even when many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills.

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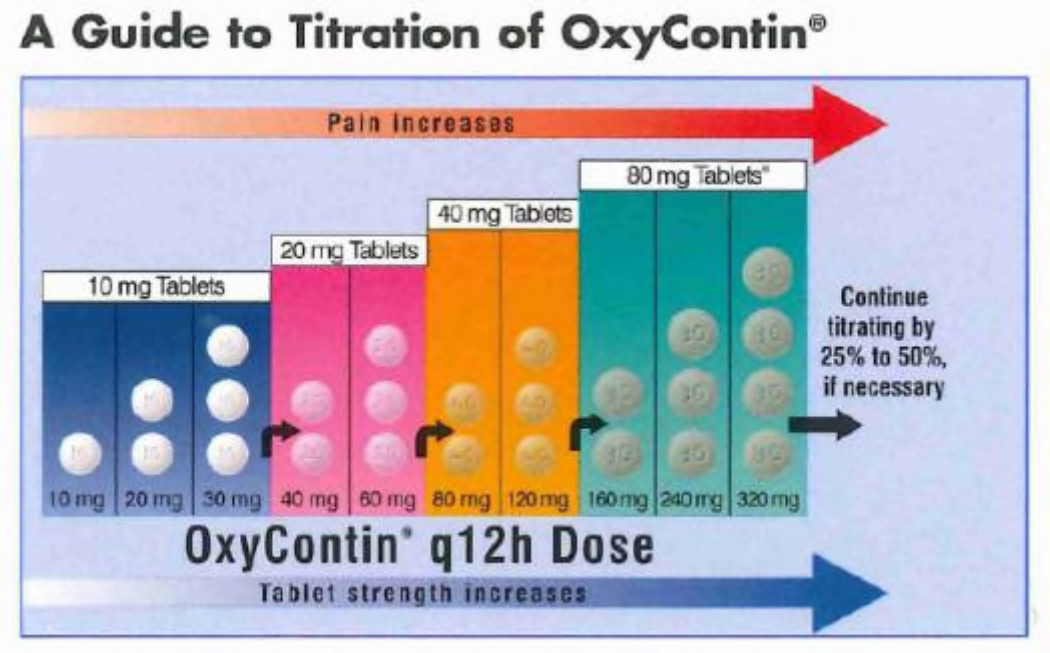
[150] *Id.*

[151] *OxyContin launch*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/oxycontin-launch-1995/.

267. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses. The manager directed representatives to discuss with physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[152]

268. As doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue directed its sales representatives to "refocus" physicians on 12-hour dosing. One sales manager instructed her team that anything shorter "needs to be nipped in the bud. NOW!!"[153]

269. These misrepresentations were incredibly dangerous. As noted above, opioid dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. Notwithstanding the risks, the 2003 Conversion Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:



270. In a 2004 response letter to the FDA, Purdue tried to address concerns that

[152] *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/.

[153] Harriet Ryan, Lisa Girion, and Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem* (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/.

patients who took OxyContin more frequently than 12 hours would be at greater risk of side effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone would not increase with more frequent dosing, and therefore no adjustments to the package labeling or 12-hour dosing regimen were needed.[154] But these claims were false, and Purdue's suggestion that there was no upper limit or risk associated with increased dosage was incredibly misleading.

271. Suggesting that it recognized the danger of its misrepresentations of no dose ceiling, Purdue discontinued the OxyContin 160 mg tablet in 2007 and stated that this step was taken "to reduce the risk of overdose accompanying the abuse of this dosage strength."[155]

272. But still Purdue and the other Manufacturing Defendants worked hard to protect their story. In March 2007, Dr. Gary Franklin, Medical Director for the Washington State Department of Labor & Industries, published the *Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain*. Developed in collaboration with providers who had extensive experience in the evaluation and treatment of patients with chronic pain, the guideline recommended a maximum daily dose of opioids to protect patients.

273. In response, Purdue sent correspondence to Dr. Franklin specifically indicating, among other things, that "limiting access to opioids for persons with chronic pain is not the answer" and that the "safety and efficacy of OxyContin doses greater than 40 mg every 12 hours in patients with chronic nonmalignant pain" was well established. Purdue even went so far as to represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a patient, "this does not preclude a trial of another opioid."

274. In 2010, Purdue published a Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin, but even the REMS does not address concerns with increasing dosage, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most

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[154] *Purdue Response to FDA, 2004*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/purdue-response-fda-2004/.

[155] *OxyContin Tablets Risk Management Program*, Purdue Pharma L.P., https://web.archive.org/web/20170215064438/https:/www.fda.gov/ohrms/dockets/DOCKETS/07p0232/07p-0232-cp00001-03-Exhibit-02-Part-1-vol1.pdf (revised May 18, 2007).

appropriate to increase the q12h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[156]

275. In 2012, APF claimed on its website that there was no "ceiling dose" for opioids for chronic pain.[157] APF also made this claim in a guide sponsored by Purdue, which is still available online.

276. Accordingly, Purdue continued to represent both publicly and privately that increased opioid usage was safe and did not present additional risk at higher doses.

277. Janssen also made the same misrepresentations regarding the disadvantages of dosage limits for other pain medicines in a 2009 patient education guide, while failing to address the risks of dosage increases with opioids.

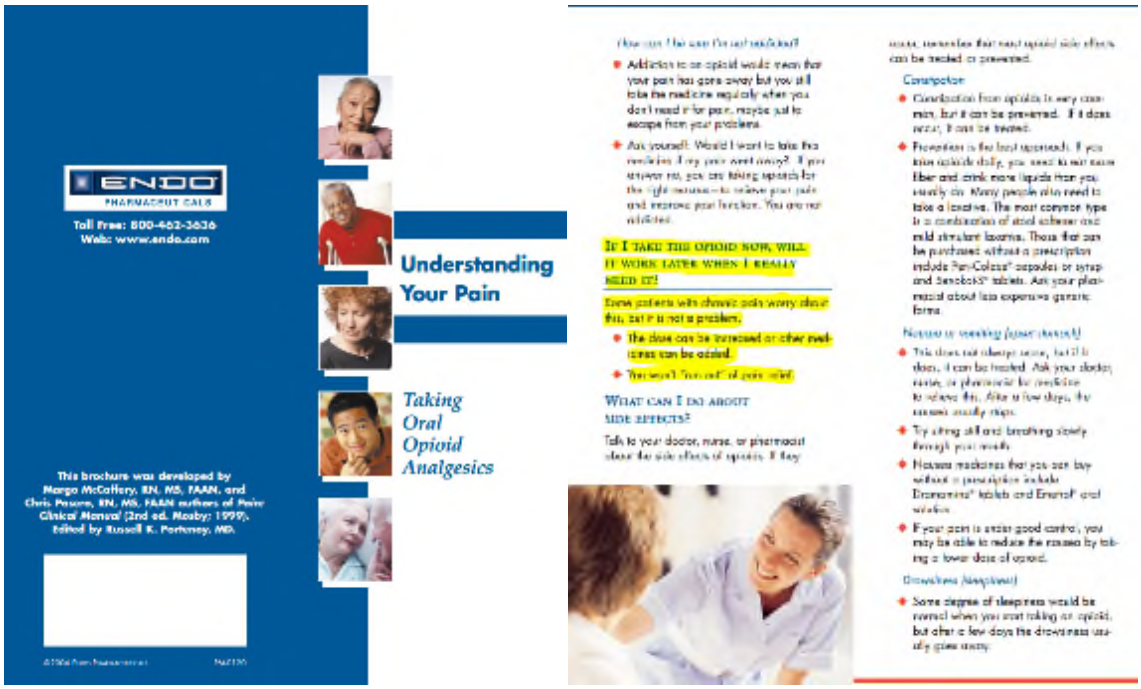
278. Endo, on a website it sponsors, PainKnowledge.com, also made the claim in 2009 that opioid dosages could be increased indefinitely.

279. In the "Understanding Your Pain" pamphlet discussed above, Endo assures opioid users that concern about developing tolerance to the drugs' pain-relieving effect is "not a problem," and that "[t]he dose can be increased" and "[y]ou won't 'run out' of pain relief."[158]

[156] *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

[157] Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC https://www.mainequalitycounts.org/image_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf (last visited July 17, 2018).

[158] *Understanding Your Pain: Taking Oral Opioid Analgesics*, *supra* note 133.



280. Dosage limits with respect to opioids are particularly important not only because of the risk of addiction but also because of the potentially fatal side effect of respiratory depression. Endo's "Understanding Your Pain" pamphlet minimized this serious side effect, calling it "slowed breathing," declaring that it is "very rare" when opioids are used "appropriately," and never stating that it could be fatal:

"Slowed breathing"

- The medical term for "slowed breathing" is "respiratory depression."
- This is very rare when oral opioids are used appropriately for pain relief.
- If you become so sleepy that you cannot make yourself stay awake, you may be in danger of slowed breathing. Stop taking your opioid and call your doctor immediately.

4. The Manufacturing Defendants falsely instructed doctors and patients that more opioids were the solution when patients presented symptoms of addiction.

281. Not only did the Manufacturing Defendants hide the serious risks of addiction associated with opioids, they actively worked to prevent doctors from taking steps to prevent or address opioid addiction in their patients.

282. One way that the Manufacturing Defendants worked to obstruct appropriate responses to opioid addiction was to push a concept called "pseudoaddiction." Dr. David Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989 coining the term, which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[159] ("Iatrogenic" describes a condition induced by medical treatment.) In other words, he claimed that people on prescription opioids who exhibited classic signs of addiction—"abnormal behavior"—were not addicted, but rather simply suffering from under-treatment of their pain. His solution for pseudoaddiction? More opioids.

283. Although this concept was formed based on a single case study, it proved to be a favorite trope in the Manufacturing Defendants' marketing schemes. For example, using this study, Purdue informed doctors and patients that signs of addiction are actually the signs of under-treated pain which should be treated with even more opioids. Purdue reassured doctors and patients, telling them that "chronic pain has been historically undertreated."[160]

284. The Manufacturing Defendants continued to spread the concept of pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing, APF wrote that "[m]any pain patients (like daily coffee drinkers) claim they are 'addicted' when they experience withdrawal symptoms associated with physical dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain . . ."[161]

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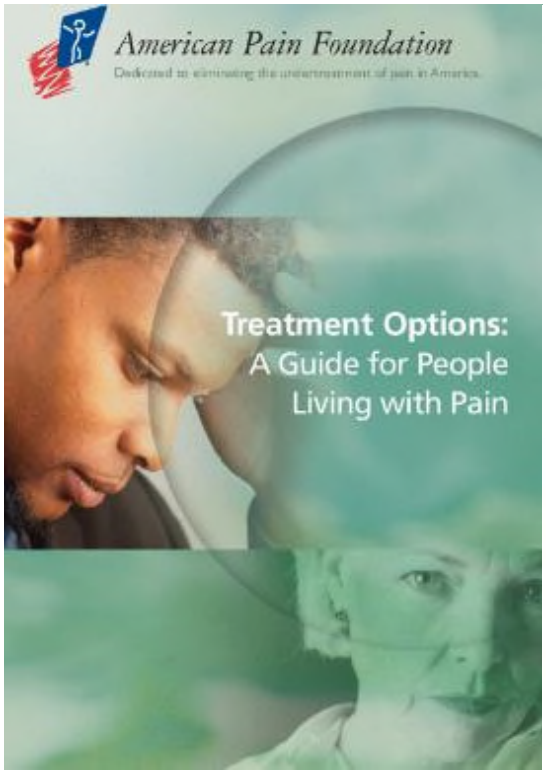
[159] David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565.

[160] *Oxycontin: Its Use and Abuse*, *supra* note 123.

[161] APF Brief Amici Curiae, *supra* note 139, at 10-11.

285. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," the APF claimed: "*Physical dependence is normal*; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted."[162] In this same publication, the APF asserted that "people who are not substance abusers" may also engage in "unacceptable" behaviors such as "increasing the dose without permission or obtaining the opioid from multiple sources," but such behaviors do not indicate addiction and instead reflect a "desire to obtain pain relief."[163]



Side effects

The most common side effects of opioids include constipation, nausea and vomiting, sedation (sleepiness), mental clouding and itching. Some people may also experience dizziness or difficulty urinating. Respiratory depression, a decreased rate and depth of breathing, is a serious side effect associated with overdose.

The good news is that most side effects go away after a few days. However, side effects may continue in some people. Constipation is most likely to persist. Some pain experts believe all patients started on an opioid also should be taking a stool softener or a laxative. Others believe that this treatment is appropriate only if a patient is prone to developing significant constipation because of advanced age, poor diet, other diseases, or the use of other constipating drugs. Your healthcare provider can give advice on what to eat and what medicines to use to treat constipation. Always make certain to drink plenty of fluids and be as active as possible.

If any of the other side effects don't go away, they can also be treated. Be certain to tell your provider if you are having any problems. Serious side effects such as delirium or respiratory depression can occur if the dose is increased too quickly, especially in someone who is just starting to take opioids. Tell your provider if you are unable to concentrate or think clearly after you have been taking an opioid for a few days. Report other medications you may be taking that make you sleepy. Do not drive when you first start taking these drugs or immediately after the dose has been increased. Most persons will adapt to these medicines over time and can drive safely while taking them for pain control. If side effects remain troublesome, your provider may switch you to a different opioid. The amount of pain relief can be maintained after such a switch and often the side effects can be reduced.

Common drugs that can cause physical dependence

- Opioids
- Stimulants
- Sedatives
- Steroids
- Certain Antidepressants
- Certain Heart Medications
- Caffeine

Tolerance, physical dependence and addiction

You and your healthcare provider may worry about tolerance, physical dependence and addiction. It's sometimes easy to confuse the meaning of these words. Tolerance refers to the situation in which a drug becomes less effective over time. However, many persons with persistent pain don't develop tolerance and stay on the same dose of opioid for a long time. Many times when a person needs a larger dose of a drug, it's because their pain is worse or the problem causing their pain has changed.

Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, gooseburnps, anxiety) if the drug is suddenly stopped or the dose is lowered too quickly. Physical dependence is normal; any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does **NOT** mean you are addicted. In fact, many non-addictive drugs can produce physical dependence. To prevent withdrawal from occurring, the dose of the medication must be decreased slowly.

If you believe that you no longer need to take the opioid medication or want to reduce the dose, it is essential to speak to your provider. They will guide you on how to decrease your dose over time to prevent the experience of withdrawal.

286. Purdue published a REMS for OxyContin in 2010, and in the associated Healthcare Provider Training Guide stated that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."[164]

287. Purdue worked, and continues to work, to create confusion about what addiction is. For example, Purdue continues to emphasize that abuse and addiction are separate and distinct

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[162] *Treatment Options: A Guide for People Living with Pain*, *supra* note 140.
[163] *Id.*
[164] *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 156.

from physical dependence. Regardless of whether these statements may be technically correct, they continue to add ambiguity over the risks and benefits of opioids.

288. Endo sponsored an NIPC CME program in 2009 which promoted the concept of pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding its projects, developing content, and reviewing NIPC materials.

289. A 2001 paper which was authored by a doctor affiliated with Janssen stated that "[m]any patients presenting to a doctor's office asking for pain medications are accused of drug seeking. In reality, most of these patients may be undertreated for their pain syndrome."[165]

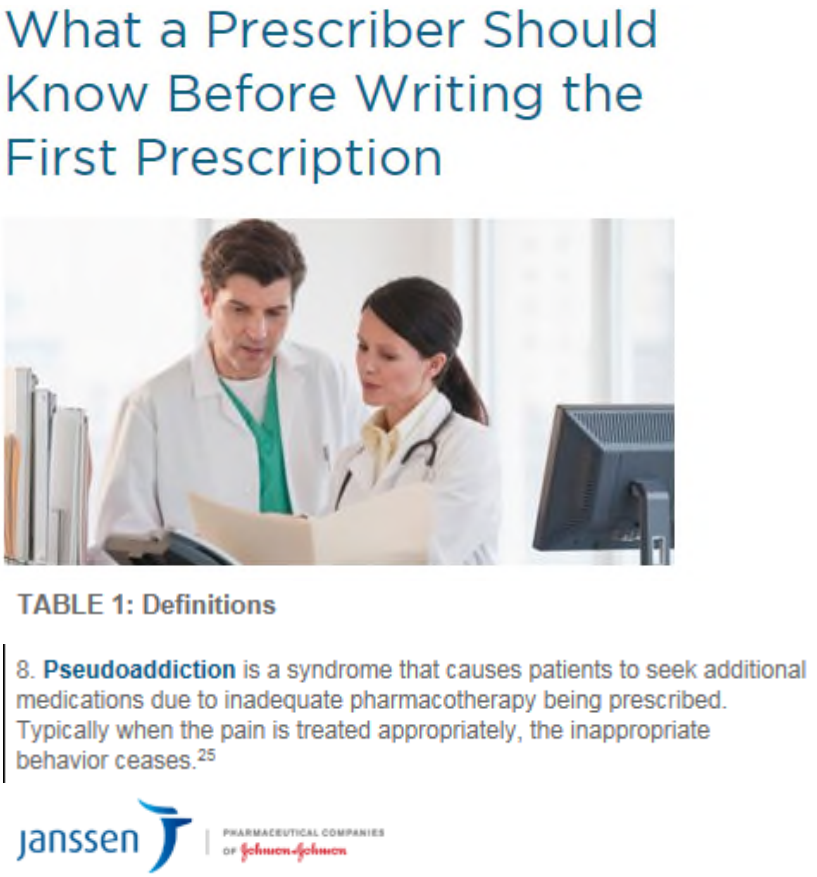
290. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different from true addiction "because such behaviors can be resolved with effective pain management."[166]

291. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases."[167]

[165] Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient and an addicted patient*, 5 European Journal of Pain 27-29 (2001), http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf.

[166] Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By Misleading Doctors, Patients*, Consumerist (May 31, 2017, 2:05pm), https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/.

[167] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription, Prescribe Responsibly*, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids, (last modified July 2, 2015).



292. As set forth in more detail below, these statements were false and misleading as evidenced by, *inter alia*, the findings made by the CDC in 2016. Indeed, there is simply no evidence that pseudoaddiction is a real phenomenon. As research compiled by the CDC and others makes clear, pseudoaddiction is pseudoscience—nothing more than a concept Defendants seized upon to help sell more of their actually addicting drugs.

5. The Manufacturing Defendants falsely claimed that risk-mitigation strategies, including tapering and abuse-deterrent technologies, made it safe to prescribe opioids for chronic use.

293. Even when the Manufacturing Defendants acknowledge that opioids pose some risk of addiction, they dismiss these concerns by claiming that addiction can be easily avoided and addressed through simple steps. In order to make prescribers feel more comfortable about starting patients on opioids, the Manufacturing Defendants falsely communicated to doctors that certain screening tools would allow them to reliably identify patients at higher risk of addiction and safely prescribe opioids, and that tapering the dose would be sufficient to manage cessation

of opioid treatment. Both assertions are false.

294. For instance, as noted above, Purdue published a REMS for OxyContin in 2010, in which it described certain steps that needed to be followed for safe opioid use. Purdue stressed that all patients should be screened for their risk of abuse or addiction, and that such screening could curb the incidence of addiction.[168]

295. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that "[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable behaviors like increasing the dose without permission or obtaining the opioid from multiple sources, among other things. Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain. It is a problem in our society that needs to be addressed through many different approaches."[169]

296. On its current website for OxyContin,[170] Purdue acknowledges that certain patients have higher risk of opioid addiction based on history of substance abuse or mental illness—a statement which, even if accurate, obscures the significant risk of addiction for all patients, including those without such a history, and comports with statements it has recently made that it is "bad apple" patients, and not the opioids, that are arguably the source of the opioid crisis:

[168] *Oxycontin Risk Evaluation and Mitigation Strategy*, *supra* note 156.
[169] *Treatment Options: A Guide for People Living with Pain*, *supra* note 140.
[170] OxyContin, https://www.oxycontin.com/index.html (last visited July 17, 2018).

> Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing OxyContin, and monitor all patients receiving OxyContin for the development of these behaviors and conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as OxyContin, but use in such patients necessitates intensive counseling about the risks and proper use of OxyContin along with intensive monitoring for signs of addiction, abuse, and misuse.

297. Additionally, on its current website, Purdue refers to publicly available tools that can assist with prescribing compliance, such as patient-prescriber agreements and risk assessments.[171]

298. Purdue continues to downplay the severity of addiction and withdrawal and claims that dependence can easily be overcome by strategies such as adhering to a tapering schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs that "[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue OxyContin."[172] And on the current OxyContin Medication Guide, Purdue also states that one should "taper the dosage gradually."[173] As a general matter, tapering is a sensible strategy for cessation of treatment with a variety of medications, such as steroids or antidepressants. But the suggestion that tapering is sufficient in the context of chronic use of potent opioids is misleading and dangerous, and sets patients up for withdrawal and addiction.

299. In its "Dear Healthcare Professional" letter in 2010, Purdue instructed doctors to gradually taper someone off OxyContin to prevent signs and symptoms of withdrawal in patients

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[171] *ER/LA Opioid Analgesics REMS*, Purdue, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/rems/ (last visited July 17, 2018).
[172] Oxycontin.com, *supra* note 166.
[173] *OxyContin Full Prescribing Information*, Purdue Pharma LP, http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o (last visited July 17, 2018).

who were physically dependent.[174] Nowhere does Purdue warn doctors or patients that tapering may be inadequate to safely end opioid treatment and avoid addiction.

300. Other Manufacturing Defendants make similar claims. For instance, Endo suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently active website, Opana.com, Endo states that assessment tools should be used to assess addiction risk, but that "[t]he potential for these risks should not, however, prevent proper management of pain in any given patient."[175]

301. On the same website, Endo makes similar statements about tapering, stating "[w]hen discontinuing OPANA ER, gradually taper the dosage."[176]

302. Janssen also states on its currently active website, PrescribeResponsibly.com, that the risk of opioid addiction "can usually be managed" through tools such as "opioid agreements" between patients and doctors.[177]

303. Each Manufacturing Defendant's statements about tapering misleadingly implied that gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking opioids.

304. The Manufacturing Defendants have also made and continue to make false and misleading statements about the purported abuse-deterrent properties of their opioid pills to suggest these reformulated pills are not susceptible to abuse. In so doing, the Manufacturing Defendants have increased their profits by selling more pills for substantially higher prices.

305. For instance, since at least 2001, Purdue has contended that "abuse resistant products can reduce the incidence of abuse."[178] Until recently, Purdue's website touted abuse-deterrent properties by saying they "can make a difference."[179]

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[174] *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 156.
[175] Opana ER, Endo Pharmaceuticals, Inc., http://www.opana.com (last visited July 17, 2018).
[176] *Id.*
[177] Heit & Gourlay, *supra* note 167.
[178] *Oxycontin: Its Use and Abuse*, *supra* note 123.
[179] *Opioids with Abuse-Deterrent Properties*, Purdue, http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited July 17, 2018); *see also*

306. On August 17, 2015, Purdue announced the launch of a new website, "Team Against Opioid Abuse," which it said was "designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids."[180] This website appears to no longer be active.

307. A 2013 study which was authored by at least two doctors who at one time worked for Purdue stated that "[a]buse-deterrent formulations of opioid analgesics can reduce abuse."[181] In another study from 2016 with at least one Purdue doctor as an author, the authors claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent formulations were introduced.[182]

308. Interestingly, one report found that the original safety label for OxyContin, which instructed patients not to crush the tablets because it would have a rapid release effect, may have inadvertently given opioid users ideas for techniques to get high from these drugs.[183]

309. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation from users to snort or inject it. But the following year, the FDA concluded:

> While there is an increased ability of the reformulated version of Opana ER to resist crushing relative to the original formulation, study data show that the reformulated version's extended-release features can be compromised when subjected to other

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https://web.archive.org/web/20180302203422/http:/www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[180] *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com,* Purdue (Aug. 17, 2015), http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/.

[181] Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics, 22 (12) Pharmacoepidemiol Drug Saf. 1274-82 (Sept. 30, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/.

[182] Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh Harikrishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterrent opioid formulation (OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 Clin. Pharmacol. Ther. 275-86 (June 22, 2016), http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full.

[183] *OxyContin Abuse and Diversion and Efforts to Address the Problem, supra* note 32.

> forms of manipulation, such as cutting, grinding, or chewing, followed by swallowing.
>
> Reformulated Opana ER can be readily prepared for injection, despite Endo's claim that these tablets have "resistance to aqueous extraction (i.e., poor syringeability)." It also appears that reformulated Opana ER can be prepared for snorting using commonly available tools and methods.
>
> The postmarketing investigations are inconclusive, and even if one were to treat available data as a reliable indicator of abuse rates, one of these investigations also suggests the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.[184]

310. Despite the FDA's determination that the evidence did not support Endo's claims of abuse-deterrence, Endo advertised its reformulated pills as "crush resistant" and directed its sales representatives to represent the same to doctors. Endo improperly marketed Opana ER as crush-resistant, when Endo's own studies showed that the pill could be crushed and ground. In 2016, Endo reached an agreement with the Attorney General of the State of New York that required Endo to discontinue making such statements.[185]

311. The Manufacturing Defendants' assertions that their reformulated pills could curb abuse were false and misleading, as the CDC's 2016 Guideline, discussed below, confirm.

312. Ultimately, even if a physician prescribes opioids after screening for abuse risk, advising a patient to taper, and selecting brand-name, abuse-deterrent formulations, chronic opioid use still comes with significant risks of addiction and abuse. The Manufacturing Defendants' statements to the contrary were designed to create a false sense of security and assure physicians that they could safely prescribe potent narcotics to their patients.

E. Research Demonstrates that the Manufacturing Defendants' Claims Are False

313. Contrary to the Manufacturing Defendants' misrepresentations about the benefits

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[184] *FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Admin. (May 10, 2013), https://wayback.archive-it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm.

[185] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement with Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

and risks of opioids, growing evidence suggests that using opioids to treat chronic pain leads to overall negative outcomes, delaying or preventing recovery and providing little actual relief, all while presenting serious risks of overdose.

314. For example, Dr. Gary Franklin, Medical Director of the Washington State Department of Labor and Industries ("L&I"), together with its chief pharmacist, Jaymie Mai, conducted a thorough analysis of all recorded deaths in that state's worker compensation system..[186] They published their findings in the *American Journal of Industrial Medicine* in 2005 and again in 2012.[187] Their research showed that the total number of opioid prescriptions paid for by the Workers' Compensation Program tripled between 1996 and 2006.[188] Not only did the number of prescriptions balloon, so too did the doses. From 1996 to 2002 the mean daily morphine equivalent dose ("MED") nearly doubled, and remained at that level through 2006.[189] As injured workers were given more prescriptions of higher doses of opioids, the rates of opioid overdoses among that population jumped, from zero in 1996 to more than twenty in 2005. And in 2009, more than thirty people receiving opioid prescriptions through the Workers' Compensation Program died of an opioid overdose.[190]

315. Additional research from L&I demonstrates that the use of opioids to treat pain after an injury actually prevents or slows a patient's recovery. In a study of employees who had suffered a low back injury on the job, Dr. Franklin determined that, among those who were prescribed opioids soon after the injury, employees who were given high doses of opioids, or for period of more than a week, were far more likely to experience negative health outcomes than

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[186] Quinones, *supra* note 42, at 203. The Washington L&I workers compensation program covers all employees in the state, except those who work for large companies or governmental entities.

[187] Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith A. Turner, Ph.D., Deborah Fulton-Kehoe, Ph.D., MPH, and Linda Grant, BSN, MBA, *Opioid dosing trends and mortality in Washington State Workers' Compensation, 1996-2002*, 48 Am J Ind Med 91-99 (2005).

[188] Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith Turner, Ph.D., Mark Sullivan, M.D., Ph.D., Thomas Wickizer, Ph.D., and Deborah Fulton-Kehoe, Ph.D., *Bending the Prescription Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline*, 55 Am J Ind Med 325, 327 (2012).

[189] *Id*. at 327-28.

[190] *Id*. at 328.

employees who were given smaller doses, or for a shorter term.

316. Specifically, the study showed that, after adjusting for the baseline covariates, injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain disabled a year later than workers with similar injuries who received no opioids at all. Similarly, those who received two prescriptions of opioids for the injury were 1.8 times more likely to remain disabled a year after their injury than workers who received no opioids at all, and those receiving daily doses higher than 150 MED were more than twice as likely to be on disability a year later, compared to workers who received no opioids.[191]

317. In sum, not only do prescription opioids present significant risks of addiction and overdose, but they also hinder patient recovery after an injury. This dynamic presents problems for employers, too, who bear significant costs when their employees do not recover quickly from workplace injuries. Employers are left without their labor force and may be responsible for paying for the injured employee's disability for long periods of time.

F. The 2016 CDC Guideline and Other Recent Studies Confirm That the Manufacturing Defendants' Statements About the Risks and Benefits of Opioids Are Patently False.

318. Contrary to the statements made by the Manufacturing Defendants in their well-orchestrated campaign to tout the benefits of opioids and downplay their risks, recent studies confirm the Manufacturing Defendants' statements were false and misleading.

319. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March 15, 2016.[192] The 2016 CDC Guideline, approved by the FDA, "provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care." The Guideline also assesses the risks and harms associated with opioid use.

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[191] Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, Early opioid prescription and subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort, 33 Spine 199, 201-202.

[192] 2016 CDC Guideline, *supra* note 33.

320. The 2016 CDC Guideline is the result of a thorough and extensive process by the CDC. The CDC issued the Guideline after it "obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee." The recommendations in the 2016 CDC Guideline were further made "on the basis of a systematic review of the best available evidence . . ."

321. The CDC went through an extensive and detailed process to solicit expert opinions for the Guideline:

> CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology. CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

322. The 2016 Guideline was also peer-reviewed pursuant to "the final information quality bulletin for peer review." Specifically, the Guideline describes the following independent peer-review process:

> [P]eer review requirements applied to this guideline because it provides influential scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations. CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified.

323. The findings in the 2016 CDC Guideline both confirmed the existing body of scientific evidence regarding the questionable efficacy of opioid use and contradicted Defendants' statements about opioids.

324. For instance, the Guideline states "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder." The Guideline further confirms there are significant symptoms related to opioid withdrawal, including drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction. These findings contradict statements made by Defendants regarding the minimal risks associated with opioid use, including that the risk of addiction from chronic opioid use is low.

325. The Guideline also concludes that there is "[n]o evidence" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain . . ." Furthermore, the Guideline indicates that "continuing opioid therapy for 3 months substantially increases the risk of opioid use disorder." Indeed, the Guideline indicates that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit." These findings flatly contradict claims made by the Defendants that there are minimal or no adverse effects of long-term opioid use, or that long-term opioid use could actually improve or restore a patient's function.

326. In support of these statements about the lack of long-term benefits of opioid use, the CDC concluded that "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." The CDC further found that "evidence is limited or insufficient for improved pain or function with long-term use

of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

327. With respect to opioid dosing, the Guideline reports that "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." The CDC specifically explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there is an "increased risk[] for opioid use disorder, respiratory depression, and death at higher dosages." As a result, the CDC advises doctors to "avoid increasing dosage" above 90 MME per day. These findings contradict statements made by Defendants that increasing dosage is safe and that under-treatment is the cause for certain patients' aberrant behavior.

328. The 2016 CDC Guideline also contradicts statements made by Defendants that there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the Guideline indicates that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

329. Finally, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes." In particular, the CDC found as follows:

> The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

Accordingly, the CDC's findings regarding "abuse-deterrent technologies" directly contradict Purdue and Endo's claims that their new pills deter or prevent abuse.

330. In addition, as discussed above, in contrast to Defendants' statements that the 1980 Porter and Jick letter provided evidence of the low risk of opioid addiction in pain patients, the NEJM recently published a letter largely debunking the use of the Porter and Jick letter as evidence for such a claim.[193] The researchers demonstrated how the Porter and Jick letter was irresponsibly cited and, in some cases, "grossly misrepresented," when in fact it did not provide evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for pain. As noted above, Dr. Jick reviewed only files of patients administered opioids in a hospital setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

331. The authors of the 2017 letter described their methodology as follows:

> We performed a bibliometric analysis of this [1980] correspondence from its publication until March 30, 2017. For each citation, two reviewers independently evaluated the portrayal of the article's conclusions, using an adaptation of an established taxonomy of citation behavior along with other aspects of generalizability . . . For context, we also ascertained the number of citations of other stand-alone letters that were published in nine contemporaneous issues of the *Journal* (in the index issue and in the four issues that preceded and followed it).
>
> We identified 608 citations of the index publication and noted a sizable increase after the introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 . . . **Of the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription, whereas some authors grossly misrepresented the conclusions of the letter** . . . Of note, affirmational citations have become much less common in recent years. In contrast to the 1980 correspondence, 11 stand-alone letters that were published contemporaneously by the Journal were cited a median of 11 times.[194] (Emphasis added).

332. The researchers provided examples of quotes from articles citing the 1980 letter, and noted several shortcomings and inaccuracies with the quotations. For instance, the researchers concluded that these quotations (i) "overstate[] conclusions of the index publication," (ii) do[] not accurately specify its study population," and (iii) did not adequately address

[193] Leung, et al., *supra* note 113.
[194] *Id.* (emphasis added).

"[l]imitizations to generalizability."[195]

Quote	Reference	Comment
"This pain population with no abuse history is literally at no risk for addiction."	Kowal N. What is the issue?: pseudoaddiction or undertreatment of pain. Nurs Econ 1998;17(6):348–9	
"In truth, however, the medical evidence overwhelmingly indicates that properly administered opioid therapy rarely if ever results in "accidental addiction" or "opioid abuse"."	Libby RT. Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Painkillers. The Independent Review 2006;10(4):511-545.	
"Fear of addiction may lead to reluctance by the physician to prescribe. [...] However, there is no evidence that this occurs when prescribing opioids for pain."	Iles S, Catterall JR, Hanks G. Use of opioid analgesics in a patient with chronic abdominal pain. Int J Clin Pract 2002;56(3):227–8.	
"In reality, medical opioid addiction is very rare. In Porter and Jick's study on patients treated with narcotics, only four of the 11,882 cases showed psychological dependency."	Liu W, Xie S, Yue L, et al. Investigation and analysis of oncologists' knowledge of morphine usage in cancer pain treatment. Onco Targets Ther 2014;7:729–37.	Overstates conclusions of the index publication does not accurately specify its study population. Limitations to generalizability are not otherwise explicitly mentioned.
"Physicians are frequently concerned about the potential for addiction when prescribing opiates; however, there have been studies suggesting that addiction rarely evolves in the setting of painful conditions."	Curtis LA, Morrell TD, Todd KH. Pain Management in the Emergency Department 2006;8(7).	
"Although medicine generally regards anecdotal information with disdain (rigorously controlled double-blind clinical trials are the "gold standard"), solid data on the low risk of addiction to opioid analgesics and the manageability of adverse side effects have been ignored or discounted in favor of the anecdotal, the scientifically unsupported, and the clearly fallacious."	Rich BA. Prioritizing pain management in patient care. Has the time come for a new approach. Postgrad Med 2001;110(3):15–7.	
"The Boston Drug Surveillance Program reviewed the charts of nearly 12,000 cancer pain patients treated over a decade and found only four of them could be labeled as addicts."	Levy MH. Pharmacologic management of cancer pain. Semin Oncol 1994;21(6):718–39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

333. Based on this review, the researchers concluded as follows:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. Our findings highlight the potential

[195] Supplementary Appendix to Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl_file/nejmc1700150_appendix.pdf.

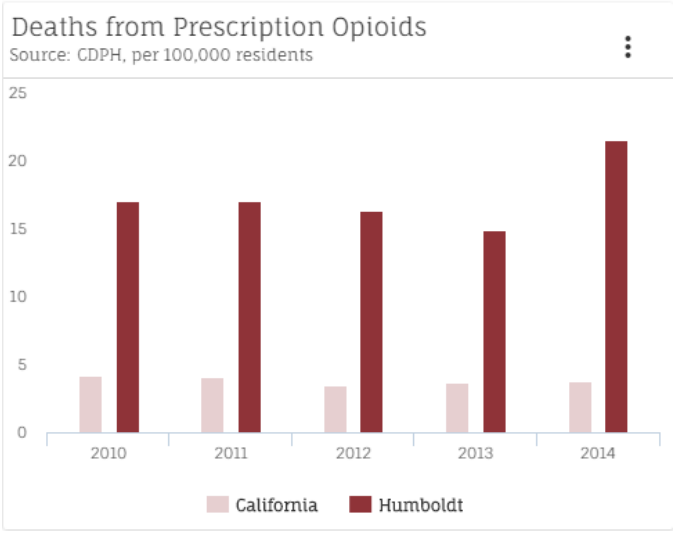
consequences of inaccurate citation and underscore the need for diligence when citing previously published studies.[196]

334. These researchers' careful analysis demonstrates the falsity of Defendants' claim that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth, with blatant disregard for the consequences of their misrepresentations.

G. Humboldt County Has Been Directly Affected by the Opioid Epidemic Caused by Defendants.

335. Humboldt County, which occupies the northwest portion of California's coast, has approximately 135,000 residents. In this predominately rural county, opioid prescriptions outnumber people. In 2016, there were 156,444 opioid prescriptions, or nearly 114.5 prescriptions per 100 residents.

336. Opioid overdose rates in Humboldt County are correspondingly high. The rate of fatal opioid overdoses is the second highest in the state, and five times higher than the national average.



337. As of 2017, on average, an unintentional drug overdose occurred in Humboldt County once every ten days. Each fatal overdose ends a life an average of 25 years early. Many fatal overdoses in Humboldt County are a result of multi-drug toxicity. The Chief Deputy

[196] Leung, et al., *supra* note 113.

Coroner has observed that it's not uncommon for people to have heroin, methamphetamine, and prescription drugs in their systems when they die from overdose.

338. Although these statistics are grim, it is likely that they could be much worse if not for the resources that the County, its residents, and local organizations have dedicated to combatting the crisis.

339. While the per-person opioid prescribing rate in Humboldt County remains high, it has steadily decreased since 2011, when 143.8 opioid prescriptions were written for every 100 people in Humboldt. The decrease is due in part to the efforts of Rx Safe Humboldt, a community coalition focused on reducing harms from opioids. Coalition members include local doctors and nurses, community members, pharmacists, public health and mental health professionals, and local organizations such as the Humboldt Independent Practice Association. The Rx Safe Humboldt coalition has focused on changing prescribing practices, providing alternative treatments for chronic pain, increasing access to medication-assisted treatment ("MAT"), increasing access to the overdose antidote naloxone, and providing safe ways to dispose of expired and used medications. Rx Safe Humboldt also created a resource guide with information on non-pharmaceutical approaches to pain management.

340. MAT involves more than medication; it is a combination of medication, counseling, and behavioral health. The medication element is critical, however, providing stability and relief from withdrawal symptoms for the individual working through recovery. Located throughout Humboldt County, the Open Door Community Health Centers have been a leader in providing MAT. The medical director of the Open Door health centers, Dr. Bill Hunter, obtained a waiver to prescribe buprenorphine in 2002, as soon as the FDA approved its use. Since that time, several other physicians at Open Door have obtained buprenorphine waivers, and the clinics now provide MAT to hundreds of Humboldt residents. Open Door has developed a care model that allows them to provide affordable treatment for opioid-use disorder within a traditional primary care clinic. The model is structured around group visits, each involving six to 12 patients. During each visit, nurses perform toxicology screenings, and drug counselors, who are often peers in recovery themselves, lead discussions, which give patients opportunities to

share their stories and offer each other support. Patients are called out one at a time to meet with their prescribing physician to review their MAT dosages and receive their new prescription.

341. In May 2018, the Redwoods Rural Health Center also began providing MAT.[197] There remains an enormous need for MAT in Humboldt County, however. As of May 2018, between 500 and 700 people are on a wait list for opioid treatment services in Humboldt and the neighboring counties of Del Norte and Trinity.[198] Aegis Treatment Centers is slated to open a 200-bed facility in Humboldt County in 2019; this facility would serve as the hub for the region in a "hub and spoke" model.

342. In addition, medical practitioners in Humboldt County are engaging in "academic detailing," using funding provided by the CDC. The academic detailing program is a two-year effort targeting three northern California counties that have been hard hit by the opioid epidemic: Humboldt, Shasta, and Lake. In Humboldt, Dr. Mary Meengs, medical director at the Humboldt Independent Practice Association, makes one-on-one calls to prescribing physicians to educate them on safe opioid prescribing practices—a direct counter to the detailing done by the Manufacturing Defendants to promote opioids, and what the Harvard Medical School professor who developed the practice calls "fighting fire with fire."[199] After receiving training and being equipped with materials and data from the CDC, Dr. Meengs delivers what is essentially a sales pitch about easing patients off prescription opioids, utilizing MAT, and writing more prescriptions for naloxone. This program of academic detailing builds on the work of Rx Safe Humboldt to change opioid prescribing practices.

343. The efforts of the community and the County have helped slow the spread of the

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[197] Kym Kemp, *With the Opioid Crisis in Humboldt County, Redwoods Rural Health Center Now Offers Treatment for Addicts*, Redheaded Blackbelt (May 16, 2018), https://kymkemp.com/2018/05/16/in-light-of-the-opioid-crisis-in-humboldt-county-redwoods-rural-health-center-now-offers-treatment-for-addicts/.

[198] Jose A. Del Real, *Needle by Needle, Crisis Grips California's Rural North*, WRAL (May 8, 2018), https://www.wral.com/needle-by-needle-crisis-grips-california-s-rural-north/17540609/.

[199] Pauline Bartolone, *Taking A Page From Pharma's Playbook To Fight The Opioid Crisis*, Washington Post (Nov. 14, 2017), https://www.washingtonpost.com/national/health-science/taking-a-page-from-pharmas-playbook-to-fight-the-opioid-crisis/2017/11/14/b3b8a350-c924-11e7-b506-8a10ed11ecf5_story.html?utm_term=.b796d56cc3a8.

opioid epidemic in Humboldt. But to truly end the crisis in Humboldt County will require resources the County does not have. The consequences of Defendants' aggressive marketing scheme and excessive distribution of prescription opioids will continue well into the future. Each day that Defendants continue to evade responsibility for the epidemic they caused, the County must continue to allocate substantial resources to address it. The costs described in the following sections are illustrative but not exhaustive examples of the significant burden the opioid crisis has imposed on the County.

1. Humboldt County has incurred health-related costs in dealing with the crisis caused by Defendants.

344. Humboldt County Department of Health and Human Services' (DHHS) Substance Use Disorder (SUD) Treatment Services assist individuals who are experiencing substance use problems that are affecting their physical health, interpersonal relationships or causing employment or legal issues. Pursuant to California state regulations, admission preference is given to pregnant women using substances and to intravenous drug users. The County's SUD treatment program offers outpatient treatment one, two, or four days per week, depending on an individual's treatment needs. Treatment is conducted in treatment groups, such as a dads' group, a women's recovery group, and a men's seeking safety group. The County provides referrals to individuals in need of services such as residential treatment, detox services, or other types of counseling. As a result of the opioid epidemic, the need for the County's SUD treatment services has risen significantly.

345. The County also allocates resources to support rehabilitation services provided by independent organizations. For example, Humboldt County Board of Supervisors allocated funds collected through Measure Z, a local sales tax dedicated to funding public safety measures, to North Coast Substance Abuse Council, Inc. in fiscal year 2015-16 and fiscal year 2017-18, for provision of inpatient rehab services.

346. The County has operated a syringe exchange program since 2000. In the past several years, the need for such services has increased significantly, and the program has been much more active, especially through DHHS's mobile outreach programs, which began in 2012.

The County's syringe exchange program also provides services like HIV and hepatitis C testing, overdose prevention training, naloxone distribution, and referrals to housing and health services. Between 2016 and 2017, the County exchanged 370,250 syringes, recorded 100 overdose reversals, had 2,736 client visits, and distributed 1,237 naloxone kits.[200] The demand for naloxone kits has climbed dramatically in recent years, at significant cost to the County. Naloxone (also sold under the brand name Narcan) is an opioid antagonist; it reverses opioid overdoses by binding to opioid receptors and thereby blocking the effects of the opioid substance, including respiratory depression. If naloxone is administered in time, it will restore the overdosing individual's airway reflexes, respiratory drive, and level of consciousness. This life-saving drug is essential, but it is expensive.

347. Humboldt County DHHS has led efforts to expand the placement and use of medication lock boxes and disposal bins to keep children safe from accessing unlocked medicine in their own homes. In partnership with community collaborators, DHHS's Public Health Branch has established disposal bins throughout the county and is actively working to expand the reach of life-saving naloxone to community members, business owners, and stakeholders. In December 2017, Humboldt County DHHS responded to community concern about syringe litter by installing two syringe disposal kiosks in Eureka. Since then, thousands of syringes, weighing nearly 55 pounds, have been safely disposed of in the kiosks. In 2018, five new syringe disposal locations were installed, adding to the County's variety of options for safe, legal, and convenient disposal of used syringes. The additional locations are part of a joint effort between Humboldt Waste Management Authority and the City of Eureka.[201]

348. The County also has a drug take-back location. This drug take-back site is essential in providing a safe, convenient, and responsible way to dispose of prescription opioids

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[200] Will Houston, *Syringe program alone won't address Humboldt County's high hepatitis infection rate, officials say*, Eureka Times-Standard (May 22, 2018, 7:03pm), http://www.times-standard.com/general-news/20180522/syringe-program-alone-wont-address-humboldt-countys-high-hepatitis-infection-rate-officials-say.

[201] *More Eureka needle disposal locations available*, Times-Standard (Mar. 5, 2018, 3:10pm), http://www.times-standard.com/general-news/20180305/more-eureka-needle-disposal-locations-available.

and minimize the potential for abuse and diversion. This take-back location is at Cloney's Pharmacy.[202]

349. Emergency response services in Humboldt County are provided by North Coast Emergency Medical Services, which also serves Del Norte County and Lake County. Humboldt County has an Emergency Medical Services Fund that guarantees payment for emergency medical care and reimburses physicians, surgeons, and hospitals for patients who are unable to pay for their own emergency medical services. The County's annual allocation to this fund is based in part on prior year actual costs, which have been affected by the increase in opioid overdoses as a result of the epidemic.

350. Humboldt DHHS is also active in numerous prevention efforts, including a five-year, youth-focused opioid grant which will invest $450,000 into the community to increase understanding of the risk of harm associated with prescription drug misuse and abuse. The effort will include community awareness campaigns, targeted education, prevention activities and data informed planning that reach youth and youth influencers. Even when grant funding supports such efforts, the County dedicates staff time and other resources to implement the programs.

351. Humboldt County has had to devote significant resources to combat the public health effects of the opioid epidemic and will continue to do so into the foreseeable future. Ultimately, however, the resources the County has dedicated to combatting the opioid epidemic result in a loss of capacity to address other important public health programs, such as communicable disease investigations, immunizations, and well-child screening.

2. The County's justice system—both criminal and civil—has incurred substantial costs in responding to the epidemic caused by Defendants.

352. The opioid epidemic has imposed serious costs and burdens on the County's criminal justice resources. As described in more detail below, the County has had more opioid-related crimes to investigate and prosecute, and the County jail now houses more people arrested or convicted for drug-related crimes. But the costs aren't limited to the criminal justice system;

[202] *Prescription Drug Safety*, Humboldt Cty. Dep't of Health & Human Services, https://humboldtgov.org/2151/Prescription-Drug-Safety (last visited July 17, 2018).

on the civil side, the County has experienced a rise in the need for child-welfare interventions, including dependency proceedings and related services. While these actions are critical to keeping people safe in the County, the services are expensive and take resources away from the other work the County could be doing.

a. Humboldt County Sheriff's Office

353. As a result of the opioid epidemic, the Sheriff's Office devotes considerable resources to responding to opioid-related crimes. The Sheriff's deputies regularly encounter persons affected by opioid use and abuse, and are exposed to syringes and needles on the job. In the Sheriff's estimation, opioids are the primary drug of choice in the County, and his deputies deal with the consequences of opioid use and abuse every day.

354. The Sheriff estimates that 75% of violent crimes in Humboldt County are drug-related. The County—in particular, the County's largest city, Eureka—has become a hub for heroin distribution in the North Coast and Southern Oregon. The amount of heroin being trafficked through the County has increased significantly in recent years. For example, in 2017, the Sheriff's Office captured ten pounds of heroin, whereas in the past, it would have been a big year to capture a pound or two of heroin in a year. Less than five months into 2018, the Sheriff's Office has already captured 12 pounds.

355. The Sheriff and his deputies have seen that both heroin and methamphetamine use can be linked to prescription opioid abuse. Many heroin users in the County started with prescription pills. In fact, one of the Sheriff's correctional deputies experienced this when he was prescribed opioids for back pain: after he could no longer get opioids through his prescription, he began using heroin. (He has since gotten clean and is now working as a drug counselor.) And many individuals use methamphetamine to counter the effects of opioid use as well as opioid withdrawal.

356. The Sheriff's Office now distributes intranasal Narcan to its entire patrol force—120 deputies. Although the overdose death rate in Humboldt County is high, County officials believe that it would be even higher without their aggressive Narcan distribution program. This program requires not only the expense of Narcan itself but also the staff time, as each of the 120

deputies has to complete a four-hour training on Narcan administration.

357. Beyond Narcan training, the opioid epidemic has created a need for deputies to have additional training, such as drug-specific first aid training and de-escalation training, both of which are 40-hour classes. Because of limited resources, however, the Sheriff's Office cannot provide all of its deputies with this training.

358. The Sheriff's Office also administers an opioid task force.

b. Probation Department and Drug Court

359. The Humboldt County Probation Department supervises adult offenders who have been granted formal probation by the court, including a community service work program, and supervises juvenile offenders. Probation officers work with offenders to reduce the likelihood to re-offend. Currently, there are 1,400 Humboldt residents on probation in low-, moderate-, or high-risk-to-reoffend categories. The effects of the opioid epidemic are apparent to the County's probation officers in their day-to-day work, and officers are able to recognize the signs of opioid abuse when people come in for their assessments.

360. The Humboldt County Probation Department also collaborates with the Humboldt County Superior Court and various local treatment providers to operate the Adult Drug Court program. Established in 1997, the program is supported by monies from the County General Fund and State tax revenues and boasts a success rate of 75 percent. In other words, three quarters of its graduates never return to the criminal system. The program works in a coordinated team approach to provide judicial oversight, community supervision, case management, and drug treatment to felony criminal offenders. Each offender undergoes an alcohol and drug assessment and is referred to an appropriate treatment program and support services.

361. Participants are provided community supervision, drug testing, substance abuse education and treatment, and other social service referrals to help them more fully integrate into the community and deal with substance-abuse-related issues. Initially, participants appear in court weekly, are tested for drug use from one to three times a week, and attend treatment programs as directed. As participants progress through the 18-month program, weekly requirements diminish.

362. Many of Drug Court's participants began their experiences of substance abuse with prescription opioids. For example, one successful graduate of the program began using opioids at age seventeen when he was prescribed a month's worth of Percocet after an injury. He rapidly consumed all of that prescription and from there, moved to buying OxyContin on the streets and snorting it, selling OxyContin to support his habit, and eventually switching to heroin because it was cheaper.[203] Humboldt County Probation Department and the Drug Court program has helped him and many others with similar stories find paths forward after their lives were derailed by Defendants' opioids.

c. Humboldt County Jail

363. The Humboldt County Jail has incurred additional costs due to the opioid epidemic. For example, the jail has spent money on acquiring equipment to screen mail and visitors coming into the jail for opioid contraband.

364. In addition, the jail provides a detox center, along with nurse support as necessary. The jail had to increase its nursing staffing due to addiction issues. As a result of the opioid epidemic, each new inmate is screened by a nurse for addiction issues; before, screening was on an as-needed basis.

365. At times it is necessary to transfer an inmate with opioid addiction issues to the hospital, and in those instances, the jail must send one or two officers to accompany the inmate.

d. Humboldt County Prosecuting Attorney's Office and Public Defender's Office

366. The Humboldt County Prosecuting Attorney's Office (PAO) represents the County in both criminal and civil matters, and is comprised of five separate divisions, including the Criminal, Civil, and Child Support Divisions. The opioid epidemic has had a significant impact on the PAO.

367. For example, the Criminal Division has seen a dramatic rise in the number of

[203] Linda Stansberry, *Humboldt County's Most Successful Addiction Treatment Program Might Be Probation*, North Coast Journal (Apr. 5, 2018), https://www.northcoastjournal.com/humboldt/humboldt-countys-most-successful-addiction-treatment-program-might-be-probation/Content?oid=8602001.

opioid-related crimes referred to the Division for prosecution. Cases involving charges such as violation of the controlled substances act and driving under the influence of opioids are now routinely part of the PAO's docket.

368. And, the Civil Division has had its opioid-related caseload increase. For example, it routinely handles cases of civil forfeitures related to opioids.

369. Family support cases involving child support have also been affected by the prevalence of opioid addiction. When children are born with opioid-use disorder or their homes are fractured because one or both parents are addicted to opioids, the County often must step in to protect the children, provide services, and address the resulting legal implications.

370. The County is also responsible for paying for public defense costs. Although not every criminal prosecution involves a public defender, the majority of them do, and they represent a significant and serious cost to the County. Indigent defense costs keep climbing.

e. Dependency Court and Superior Court

371. Humboldt County Dependency Court has been affected by the opioid epidemic in the rising number of children in the dependency system, after opioid abuse prevents parents from being able to safely care for their children. Once the dependency proceedings have started, the children then require foster families, CASA volunteers, and court clerk and staffing hours, as well as attorney and court costs. Many children in the dependency system also end up in legal problems of their own, including substance abuse, truancy, and criminal behavior.

372. As noted above, the number of dependency filings has risen sharply against the background of the opioid epidemic. Each dependency filing generates multiple court hearings and requires significant staffing and court resources.

373. Dependency Court also has hearings for infants with a positive toxicity screen due to in-utero exposure to opioids. The County appoints a lawyer to represent each child.

374. The Superior Court of Humboldt County has also been affected by the opioid epidemic as a result of its increased caseload. For example, crimes like criminal trespass, possession of drug paraphernalia, generic possession, theft, and malicious mischief are often directly related to opioid use. The court's costs are tied to filings, and the increased caseload

brings increased costs.

3. Humboldt County Parks and Trails department has been affected by Defendants' conduct.

375. The County's Parks and Trails department has also been affected by the opioid epidemic. The Humboldt County Parks and Trails system features 17 park units (nearly 950 acres) and the five-mile-long Hammond Trail in McKinleyville. County Parks include ten beach parks, five parks with river access, five boat ramps, and five campgrounds.

376. Parks and Trails staff operate and maintain recreational facilities and manage the land for public safety and resource protection and conservation. Parks and Trails staff maintain park facility infrastructure including restrooms, water and wastewater systems, showers, campsites, caretaker residences, boat ramps, parking areas, playground equipment, a seasonal dam, signs and fences, and various amenities.

377. The Parks and Trails department and the people who use the Humboldt County parks are affected by the opioid crisis in a variety of ways, but primarily via exposure to used needles. For example, Parks and Trails staff have found used needles and syringes in park restrooms, garbage cans, parking lots, and flower beds. Janitorial, maintenance, and park managers must take precautions, as exposure to such needles carries a risk of infection from blood-borne pathogens. The safe disposal of used needles and syringes requires additional time and resources.

4. The opioid epidemic has also contributed to homelessness in Humboldt County.

378. The opioid epidemic has also compounded the issue of homelessness in Humboldt County. Although the causes of homelessness are multi-faceted and complex, substance abuse is both a contributing cause and result of homelessness. Opioid-use disorder is a significant factor that prevents individuals from maintaining economic well-being and housing stability. Additionally, while the leading cause of death among homeless Americans used to be HIV, it is now drug overdose. A study published in JAMA Internal Medicine found that overdoses were the leading cause of death among individuals experiencing homelessness in the Boston area. Of

the overdose deaths, 81% involved opioids.[204]

379. In Humboldt County, the opioid epidemic has corresponded to an increase in the homeless population, and opioid use and abuse compound the issues underlying homelessness and make it more difficult for the County to address.

380. In sum, Humboldt County has devoted and continues to devote its resources to responding to the opioid crisis. But, its response comes at a significant cost to the County. And, even with its robust, proactive approach to the epidemic, the County does not have the enormous resources it would take to fully address and end the ongoing crisis.

5. The opioid crisis has also caused lost productivity to the City.

381. Humboldt County is self-insured for all worker compensation risk and claims.

382. When someone working for the County is injured on the job, the County pays, among other things, that person's health care costs, including the cost of prescription opioids.

383. The majority of opioid prescriptions related to these workers' compensation claims are unnecessary, as the injuries are typically back strains, joint pain, and other injuries that should be treated with physical therapy, lidocaine patches, and other non-opioid therapies.

384. Yet because of the Manufacturing Defendants' marketing efforts, the County, in connection with its workers' compensation programs, purchased unnecessary prescription opioids which it should have never paid for. Furthermore, under its workers' compensation plan, the County pays for doctors' visits, lab work, and other costs related to the prescription of opioid painkillers.

385. Had Defendants told the truth about the risks and benefits of opioids, the County would not have had to pay for these drugs or the costs related to their prescription.

386. Not only are opioids inappropriate for treating the majority of individuals making workers' compensation claims, the use of opioids often actually slows the recovery process. This means that the injured worker is off the job longer, and the County shoulders higher workers'

[204] Travis P. Baggett, MD, MPH, Stephen W. Hwang, MD, MPH, James J. O'Connell, MD, et al., *Mortality Among Homeless Adults in Boston, Shifts in Causes of Death Over a 15-Year Period*, 173 (3) JAMA Intern Med 189-95 (2013), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1556797#qundefined.

compensation costs in connection with the lost productivity of these individuals.

H. No Federal Agency Action, Including by the FDA, Can Provide the Relief Humboldt County Seeks Here.

387. The injuries Humboldt County has suffered and will continue to suffer cannot be addressed by agency or regulatory action. There are no rules the FDA could make or actions the agency could take that would provide Humboldt County the relief it seeks in this litigation.

388. Even if prescription opioids were entirely banned today or only used for the intended purpose, millions of Americans, including Humboldt residents, would remain addicted to opioids, and overdoses will continue to claim lives. The Sheriff's Office will continue to spend extraordinary resources combatting illegal opioid sales, and the Prosecuting Attorney's Office and Humboldt County courts will remain burdened with opioid-related crimes and dependency hearings. Social services and public health efforts will be stretched thin.

389. Regulatory action would do nothing to compensate the County for the money and resources it has already expended addressing the impacts of the opioid epidemic and the resources it will need in the future. Only this litigation has the ability to provide the County with the relief it seeks.

390. Furthermore, the costs Humboldt County has incurred in responding to the opioid crisis and in rendering public services described above are recoverable pursuant to the causes of actions raised by the County. Defendants' misconduct alleged herein is not a series of isolated incidents, but instead the result of a sophisticated and complex marketing scheme over the course of more than twenty years that has caused a substantial and long-term burden on the municipal services provided by the County. In addition, the public nuisance created by Defendants and the County's requested relief in seeking abatement further compels Defendants to reimburse and compensate Humboldt County for the substantial resources it has expended to address the opioid crisis.

V. CLAIMS FOR RELIEF

COUNT ONE — VIOLATIONS OF CALIFORNIA'S UNFAIR COMPETITION LAW CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.*

391. Humboldt County re-alleges and incorporates by reference each of the allegations contained in the proceedings paragraphs of this Complaint as though fully alleged herein.

392. Humboldt County brings this claim by agreement with the Humboldt County District Attorney, pursuant to California's Unfair Competition Law, Cal. Bus. & Prof. Code § 17204.

393. California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* ("UCL"), protects both consumers and competitors by promoting fair competition in commercial markets for goods and services. The UCL is interpreted broadly and provides a cause of action for "any unlawful, unfair, or fraudulent business act or practice." Any unlawful, unfair, or fraudulent business practice that causes injury to consumers falls within the ambit of the UCL.

394. Defendants have engaged in unlawful, unfair, and fraudulent business practices in violation of the UCL as set forth above.

395. As a direct and proximate result of the foregoing acts and practices, Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of the UCL described in this Complaint. The County therefore seeks restitution from Defendants pursuant to Business & Professions Code § 17535.

396. As a direct and proximate result of the foregoing acts and practices, Defendants have obtained an unfair advantage over similar businesses that have not engaged in such practices.

397. Humboldt County seeks the maximum civil penalties permitted by law as a result of the public nuisance created by Defendants in violation of Humboldt County Code §§ 351-1 *et seq.* and the UCL.

COUNT TWO — PUBLIC NUISANCE

398. Humboldt County re-alleges and incorporates by reference each of the allegations

contained in the preceding paragraphs of this Complaint as though fully alleged herein.

399. California Civil Code § 3479 provides that "[a]nything that is injurious to health…or is indecent or offensive to the senses, or an obstruction to the free use of property, so as to interfere with the comfortable enjoyment of life or property…is a nuisance." "A public nuisance is one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon individuals may be unequal." Cal. Civ. Code § 3480.

400. California tort law is to the same effect. Any conduct which interferes with the interests of the community or the comfort and convenience of the general public, including interference with the public health, comfort, and convenience, is a public nuisance.

401. As set forth above, Manufacturing Defendants' actions and omissions include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these actions and omissions unreasonably and significantly interfered with the public health, comfort, and convenience in Humboldt County.

402. As set forth above, Distributor Defendants distributed enormous quantities of potent narcotics that far exceeded quantities that could reasonably be expected to be for legitimate medical use. Despite knowing the risk of diversion, Defendants failed to adequately monitor, report, and halt orders that were suspicious by nature of their frequency and volume. These acts significantly interfered with the public health, comfort, and convenience in Humboldt County.

403. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

404. The public nuisance is substantial and unreasonable. Defendants' actions caused

and continue to cause the public health epidemic described above in Humboldt County, and the resulting harm to the County's property outweighs any offsetting benefit.

405. Each Defendant is liable for public nuisance because it has created a condition that is injurious to health and an obstruction to the free use of property, interfering with the comfortable enjoyment of life and property.

406. Humboldt County seeks all legal and equitable relief available under law, including damages, attorney fees, and costs.

COUNT THREE — NEGLIGENCE AND GROSS NEGLIGENCE

407. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

408. A cause of action arises for negligence when a defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury. *Ladd v. County of San Mateo*, 12 Cal.4th 913, 917, 443 P.2d 561 (1996).

409. Each Defendant owed a duty of care to Humboldt County, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

410. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in Humboldt County by misrepresenting the risks and benefits associated with opioids and by distributing dangerous quantities of opioids.

411. As set forth above, Manufacturing Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid doses indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to Humboldt County.

412. Distributor Defendants negligently distributed enormous quantities of potent

narcotics and failed to report such distributions. Distributor Defendants violated their duty of care by moving these dangerous products into Humboldt County in such quantities, facilitating diversion, misuse, and abuse of opioids.

413. Defendants' misconduct constitutes a lack of even scant care and an extreme departure from the ordinary standard of conduct.

414. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Plaintiff has suffered and will continue to suffer harm, and is entitled to damages in an amount determined at trial.

COUNT FOUR — UNJUST ENRICHMENT

415. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

416. Each Defendant was required to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

417. Rather than prevent or mitigate the wide proliferation of opioids into Humboldt County, each Defendant instead chose to place its monetary interests first and each Defendant profited from prescription opioids sold in Humboldt County.

418. Each Defendant also failed to maintain effective controls against the unintended and illegal use of the prescription opioids it manufactured or distributed, again choosing instead to place its monetary interests first.

419. Each Defendant therefore received a benefit from the sale and distribution of prescription opioids to and in Humboldt County, and these Defendants have been unjustly enriched at the expense of Humboldt County.

420. As a result, Humboldt County is entitled to damages on its unjust enrichment claim in an amount to be proven at trial.

COUNT FIVE — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, *ET SEQ*.

421. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this complaint.

422. This claim is brought by Humboldt County against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, *et seq*.

423. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

424. Plaintiff is a "person," as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of the Defendants' wrongful conduct described herein.

425. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . . " 18 U.S.C. § 1962(c).

426. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

427. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

A. Description of the Defendants' Enterprises

428. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

429. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

430. Defendants formed two such association-in-fact enterprises—referred to herein as "the Promotion Enterprise" and "the Diversion Enterprise."

431. The Promotion Enterprise consists of the Manufacturing Defendants, Front Groups, and KOLs. In particular, the Enterprise consists of (a) Defendant Purdue, including its employees and agents, (b) Defendant Endo, including its employees and agents, (c) Defendant Janssen, including its employees and agents, (d) Defendant Cephalon, including its employees and agents, (e) Defendant Actavis, including its employees and agents, and (f) Defendant Mallinckrodt, including its employees and agents (collectively, "Manufacturing Defendants"); certain front groups described above, including but not limited to (a) the American Pain Foundation, including its employees and agents, (b) the American Academy of Pain Medicine, including its employees and agents, and (c) the American Pain Society, including its employees and agents (collectively, the "Front Groups"); and certain Key Opinion Leaders, including but not limited to (a) Dr. Russell Portenoy, (b) Dr. Perry Fine, (c) Dr. Lynn Webster, and (d) Dr. Scott Fishman (collectively, the "KOLs"). The entities in the Promotion Enterprise acted in concert to create demand for prescription opioids.

432. Alternatively, each of the above-named Manufacturing Defendants and Front Groups constitutes a single legal entity "enterprise" within the meaning of 18 U.S.C. § 1961(4), through which the members of the enterprise conducted a pattern of racketeering activity. The separate legal status of each member of the Enterprise facilitated the fraudulent scheme and provided a hoped-for shield from liability for Defendants and their co-conspirators.

433. Alternatively, each of the Manufacturing Defendants, together with the Distributor Defendants, the Front Groups, and the KOLs, constitute separate, associated-in-fact Enterprises within the meaning of 18 U.S.C. § 1961(4).

434. The Diversion Enterprise consists of all Defendants. In particular, the Enterprise consists of (a) Defendant Purdue, including its employees and agents, (b) Defendant Endo, including its employees and agents, (c) Defendant Janssen, including its employees and agents, (d) Defendant Cephalon, including its employees and agents, (e) Defendant Actavis, including its employees and agents, (f) Defendant Mallinckrodt, including its employees and agents, (g) Defendant AmerisourceBergen, including its employees and agents, (h) Defendant Cardinal

Health, including its employees and agents, and (i) Defendant McKesson, including its employees and agents (collectively, "Defendants").

435. The CSA and its implementing regulations require all manufacturers and distributors of controlled substances, including opioids, to maintain a system to identify and report suspicious orders, including orders of unusual size or frequency, or orders deviating from a normal pattern, and maintain effective controls against diversion of controlled substances. *See* 21 U.S.C. § 823; 21 C.F.R. §1301.74(b). The Manufacturing Defendants and the Distributor Defendants alike are required to become "registrants" under the CSA, 21 U.S.C. § 823(a)-(b), and its implementing regulations, which provide that "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance. . . shall obtain a registration[.]" 21 C.F.R. § 1301.11(a). Defendants' duties as registrants include reporting suspicious orders of controlled substances, which are defined as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

436. The Manufacturing Defendants carried out the Diversion Enterprise by incentivizing and supplying suspicious sales of opioids, despite their knowledge that their opioids were being diverted to illicit use, and by failing to notify the DEA of such suspicious orders as required by law. The Distributor Defendants carried out the Diversion Enterprise by failing to maintain effective controls against diversion, intentionally evading their obligation to report suspicious orders to the DEA, and conspiring to prevent limits on the prescription opioids they were oversupplying to communities like Plaintiff.

437. The Promotion Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to sell highly addictive opioids for treatment of chronic pain while knowing that opioids have little or no demonstrated efficacy for such pain and have significant risk of addiction, overdose, and death.

438. The Distribution Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained

systematic links for a common purpose: to distribute highly addictive opioids in quantities that far exceeded amounts that could reasonably be considered medically necessary.

439. To accomplish these purposes, the Promotion Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for Defendants' opioid medications (the "Promotion Scheme"), and the Diversion Enterprise carried out a scheme to systematically disregard, avoid, or frustrate the monitoring and reporting requirements intended to prevent the widespread distribution of dangerous controlled substances (the "Diversion Scheme"). The Promotion Scheme and the Diversion Scheme are collectively referred to as the "Schemes."

B. The Enterprises Sought to Fraudulently Increase Defendants' Profits and Revenues

440. At all relevant times, each Defendant was aware of the conduct of the Enterprises, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales and distribution of prescription opioids. In addition, the Front Groups and KOLs received direct payments from the Manufacturing Defendants in exchange for their role in the Promotion Enterprise, and to advance the Promotion Enterprise's fraudulent marketing scheme.

441. The Enterprises engaged in, and their activities affected, interstate and foreign commerce because they involved commercial activities across state boundaries, including but not limited to: (1) the marketing, promotion, and distribution of prescription opioids; (2) advocacy at the state and federal level for change in the law governing the use and prescription of prescription opioids; (3) the issuance of prescriptions and prescription guidelines for opioids; (4) the issuance of fees, bills, and statements demanding payment for prescriptions of opioids; (5) payments, rebates, and chargebacks between Defendants; and (6) the creation of documents, reports, and communications related to Defendants' reporting requirements under the CSA and its implementing regulations.

442. The persons engaged in the Enterprises are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. With respect to the Promotion Enterprise, each Manufacturing Defendant funded

and directed the operations of the KOLs and the Front Groups; in fact, the board of directors of each of the Front Groups are and were full of doctors who were on the Manufacturing Defendants' payrolls, either as consultants or speakers at medical events. Moreover, each Manufacturing Defendant coordinated and, at times, co-funded their activities in furtherance of the goals of the Enterprise. This coordination can also be inferred through the consistent misrepresentations described below. With respect to the Diversion Enterprise, Defendants were financially linked through a system of payments, rebates, and chargebacks.

443. In the Promotion Enterprise, there is regular communication between each Manufacturing Defendant, each of the Front Groups, and each KOL in which information regarding the Defendants' scheme to increase opioid prescriptions is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Manufacturing Defendants, the Front Groups, and the KOL share information regarding the operation of the Promotion Enterprise.

444. In the Diversion Enterprise, there is regular communication between each Defendant in which information regarding the Defendants' scheme to oversupply opioids and avoid restrictive regulations or quotas is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants share information regarding the operation of the Diversion Enterprise.

445. The Enterprises functioned as continuing units for the purposes of executing the Schemes, and when issues arose during the Schemes, each member of the Enterprises agreed to take actions to hide the Schemes and the existence of the Enterprises.

446. Each Defendant participated in the operation and management of the Enterprises by directing its affairs as described herein.

447. While Defendants participate in, and are members of, the Enterprises, they have an existence separate from the Enterprises, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

448. Each Manufacturing Defendant orchestrated the affairs of the Promotion Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making

misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives to promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Promotion Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups, including the American Pain Foundation and the Pain & Policy Studies Group; (6) sponsoring CME programs that claimed that opioid therapy has been shown to reduce pain and depressive symptoms; (7) supporting and sponsoring guidelines indicating that opioid medications are effective and can restore patients' quality of life; (8) retaining KOLs to promote the use of opioids; and (9) concealing the true nature of their relationships with the other members of the Promotion Scheme, and the Promotion Enterprise, including the Front Groups and the KOLs.

449. The Front Groups orchestrated the affairs of the Promotion Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids described herein; (2) holding themselves out as independent advocacy groups, when in fact their operating budgets are entirely comprised of contributions from opioid drug manufacturers; (3) publishing treatment guidelines that advised the prescription of opioids; (4) sponsoring medical education programs that touted the benefits of opioids to treat chronic pain while minimizing and trivializing their risks; and (5) concealing the true nature of their relationship with the other members of the Promotion Enterprise.

450. The KOLs orchestrated the affairs of the Promotion Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as independent, when in fact they are systematically linked to and funded by opioid drug manufacturers; and (3) concealing the true nature of their relationship with the other members of the Promotion Enterprise.

451. Without the willing participation of each member of the Promotion Enterprise, the Promotion Scheme and the Promotion Enterprise's common course of conduct would not have been successful.

452. Each Distributor Defendant orchestrated the affairs of the Diversion Enterprise and exerted substantial control over the Diversion Enterprise by, at least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) providing the Manufacturing Defendants with data regarding their prescription opioid sales, including purchase orders and ship notices; (3) accepting payments from the Manufacturing Defendants in the form of rebates and/or chargebacks; (4) filling suspicious orders for prescription opioids despite having identified them as suspicious and knowing opioids were being diverted into the illicit drug market; (5) working with other members of the Enterprise through groups like the Healthcare Distribution Alliance to ensure the free flow of opioids, including by supporting limits on the DEA's ability to use immediate suspension orders; and (6) concealing the true nature of their relationships with the other members of the Diversion Enterprise.

453. Each Manufacturing Defendant orchestrated the affairs of the Diversion Enterprise and exerted substantial control over the Diversion Enterprise by, at least: (1) refusing or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) obtaining from the Distributor Defendants data regarding their prescription opioid sales, including purchase orders and ship notices; (3) providing payments to the Distributor Defendants in the form of rebates and/or chargebacks; (4) working with other members of the Diversion Enterprise through groups like the Healthcare Distribution Alliance to ensure the free flow of opioids, including by supporting limits on the DEA's ability to use immediate suspension orders; and (5) concealing the true nature of their relationships with the other members of the Diversion Enterprise.

454. Without the willing participation of each member of the Diversion Enterprise, the Diversion Scheme and the Diversion Enterprise's common course of conduct would not have been successful.

C. Predicate Acts: Mail and Wire Fraud

455. To carry out, or attempt to carry out, the Schemes, the members of the Enterprises, each of whom is a person associated-in-fact with the Enterprises, did knowingly conduct or participate in, directly or indirectly, the affairs of the Enterprises through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

456. Specifically, the members of the Enterprises have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

457. The multiple acts of racketeering activity which the members of the Enterprises committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

458. The racketeering activity was made possible by the Enterprises' regular use of the facilities, services, distribution channels, and employees of the Enterprises.

459. The members of the Enterprises participated in the Schemes by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

460. The members of the Enterprises used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their Schemes through common misrepresentations, concealments, and material omissions.

461. In devising and executing the illegal Schemes, the members of the Enterprises devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

462. For the purpose of executing the illegal Schemes, the members of the Enterprises committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal Schemes.

463. The Enterprises' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

A. Mail Fraud: The members of the Enterprises violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling and distributing excessive quantities of highly addictive opioids.

B. Wire Fraud: The members of the Enterprises violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling and distributing excessive quantities of highly addictive opioids.

464. The Manufacturing Defendants falsely and misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the following: Defendant Purdue's (1) May 31, 1996 press release announcing the release of OxyContin and indicating that the fear of OxyContin's addictive properties was exaggerated; (2) 1990 promotional video in which Dr. Portenoy, a paid Purdue KOL, understated the risk of opioid addiction; (3) 1998 promotional video which misleadingly cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (4) statements made on its 2000 "Partners Against Pain" website which claimed that the addiction risk of OxyContin was very low; (5) literature distributed to physicians which misleadingly cited a 1980 NEJM letter in support of the use of opioids to treat chronic pain; (6) August 2001 statements to Congress by Purdue Executive Vice President and Chief Operating Officer Michael Friedman regarding the value of OxyContin in treating chronic pain; (7) patient brochure entitled "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain" indicating that OxyContin is non-addicting; (8) 2001 statement by Senior Medical Director for Purdue, Dr. David Haddox, indicating that the 'legitimate' use of OxyContin would not result in addiction; (9) multiple sales representatives' communications regarding the low risk of addiction associated with opioids; (10) statements included in promotional materials for opioids distributed to doctors via the mail and wires; (11) statements in a 2003 Patient Information Guide distributed by Purdue indicating that addiction to opioid analgesics in properly managed patients with pain has been reported to be rare; (12) telephonic and electronic communications to doctors and patients indicating that

signs of addiction in the case of opioid use are likely only the signs of under-treated pain; (13) statements in Purdue's Risk Evaluation and Mitigation Strategy for OxyContin indicating that drug-seeking behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior; (14) statements made on Purdue's website and in a 2010 "Dear Healthcare Professional" letter indicating that opioid dependence can be addressed by dosing methods such as tapering; (15) statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin indicating that long-term opioid use improves patients' function and quality of life; (18) statements made in advertising and a 2007 book indicating that pain relief from opioids improve patients' function and quality of life; (19) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (20) electronic and telephonic communications concealing its relationship with the other members of the Enterprises.

465. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made, beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that patients who take opioids as prescribed usually do not become addicted; (2) statements made on another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do not become addicted to opioid medications; (3) statements in pamphlets and publications described by Endo indicating that most people who take opioids for pain relief do not develop an addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use does not result in addiction; (5) statements made on the Endo-run website, Opana.com, indicating that opioid dependence can be addressed by dosing methods such as tapering; (6) statements made on its website, PainKnowledge.com, that opioid dosages could be increased indefinitely; (7) statements made in a publication entitled "Understanding Your Pain: Taking Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely; (8) electronic and telephonic communications to its sales representatives indicating that the formula

for its medicines is 'crush resistant;' (9) statements made in advertisements and a 2007 book indicating that pain relief from opioids improves patients' function and quality of life; (10) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (11) telephonic and electronic communications concealing its relationship with the other members of the Enterprises.

466. Defendant Janssen made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements on its website, PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated; (2) statements in a 2009 patient education guide claiming that opioids are rarely addictive when used properly; (3) statements included on a 2009 Janssen-sponsored website promoting the concept of opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, advocating the concept of opioid pseudoaddiction; (5) statements on its website, PrescribeResponsibly.com, indicating that opioid addiction can be managed; (6) statements in its 2009 patient education guide indicating the risks associated with limiting the dosages of pain medicines; (7) telephonic and electronic communications by its sales representatives indicating that opioids will improve patients' function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Enterprises.

467. The American Academic of Pain Medicine made false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a 2009 patient education video entitled "Finding Relief: Pain Management for Older Adults" indicating the opioids are rarely addictive; and (2) telephonic and electronic communications concealing its relationship with the other members of the Promotion Enterprise.

468. The American Pain Society Quality of Care Committee made a number of false or misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a May 31, 1996 press release in which the organization claimed there is very little risk of addiction from the proper use of drugs for pain relief; and (2) telephonic and electronic communications concealing its relationship with the other members of the Promotion Enterprise.

469. The American Pain Foundation ("APF") made a number of false and misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made by an APF Executive Director to Congress indicating that opioids only rarely lead to addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment of chronic pain; (3) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that the risks of addiction associated with opioid prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that opioid users are not "actual addicts"; (5) statements made in a 2007 publication entitled "Treatment Options: A Guide for People Living with Pain" indicating that even physical dependence on opioids does not constitute addiction; (6) claims on its website that there is no ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that opioids can improve daily function; and (8) telephonic and electronic communications concealing its relationship with the other members of the Promotion Enterprise.

470. The KOLs, including Drs. Russell Portenoy, Perry Fine, Scott Fishman, and Lynn Webster, made a number of misleading statements in the mail and wires in violation of 18 U.S.C. § 1341 and § 1343, described above, including statements made by Dr. Portenoy in a promotional video indicating that the likelihood of addiction to opioid medications is extremely low. Indeed, Dr. Portenoy has since admitted that his statements about the safety and efficacy of opioids were false.

471. The Manufacturing Defendants and Distributor Defendants falsely and misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include the following: (1) the transmission of documents and communications regarding the sale, shipment, and delivery of excessive quantities of prescription opioids, including invoices and shipping records; (2) the transmission of documents and communications regarding their requests for higher aggregate production quotas, individual manufacturing quotas, and procurement quotas; (3) the transmission of reports to the DEA that did not disclose suspicious orders as required by law; (4) the transmission of documents and

communications regarding payments, rebates, and chargebacks; (5) the transmission of the actual payments, rebates, and chargebacks themselves; (6) correspondence between Defendants and their representatives in front groups and trade organizations regarding efforts to curtail restrictions on opioids and hobble DEA enforcement actions; (7) the submission of false and misleading certifications required annually under various agreements between Defendants and federal regulators; and (8) the shipment of vast quantities of highly addictive opioids. Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

472. In addition, the Distributor Defendants misrepresented their compliance with laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion into the illicit market. At the same time, the Distributor Defendants misrepresented the effectiveness of their monitoring programs, their ability to detect suspicious orders, their commitment to preventing diversion of prescription opioids, and their compliance with regulations regarding the identification and reporting of suspicious orders of prescription opioids.

473. The mail and wire transmissions described herein were made in furtherance of Defendants' Schemes and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them; increase the prescription rate for opioid medications; and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain, and to deceive regulators and the public regarding Defendants' compliance with their obligations to identify and report suspicious orders of prescription opioids, while Defendants intentionally enabled millions of prescription opioids to be deposited into communities across the United States, including in Humboldt County. Defendants' scheme and common course of conduct was intended to increase or maintain high quotas for the manufacture and distribution of prescription opioids and their corresponding high profits for all Defendants.

474. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to

Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the Schemes.

475. The members of the Enterprises have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the members of the Enterprises conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants and the members of the Enterprises in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or minimize losses for the Defendants and their named and unnamed co-conspirators throughout the illegal scheme and common course of conduct.

476. The members of the Enterprises aided and abetted others in the violations of the above laws.

477. To achieve their common goals, the members of the Enterprises hid from Plaintiff and the public: (1) the fraudulent nature of the Manufacturing Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with prescription opioids; (3) the fraudulent nature of the Distributor Defendants' representations regarding their compliance with requirements to maintain effective controls against diversion and report suspicious orders of opioids; and (4) the true nature of the relationship between the members of the Enterprises.

478. Defendants and each member of the Enterprises, with knowledge and intent, agreed to the overall objectives of the Schemes and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprises and their co-conspirators had to agree to conceal their fraudulent scheme.

479. The members of the Enterprises knew, and intended that, Plaintiff and the public would rely on the material misrepresentations and omissions made by them and suffer damages as a result.

480. As described herein, the members of the Enterprises engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiff and the public based on their misrepresentations and omissions.

481. The predicate acts also had the same or similar results, participants, victims, and methods of commission.

482. The predicate acts were related and not isolated events.

483. The true purposes of Defendants' Schemes were necessarily revealed to each member of the Enterprises. Nevertheless, the members of the Enterprises continued to disseminate misrepresentations regarding the nature of prescription opioids and the functioning of the Schemes.

484. Defendants' fraudulent concealment was material to Plaintiff and the public. Had the members of the Enterprises disclosed the true nature of prescription opioids and their excessive distribution, Humboldt County would not have acted as it did or incurred the substantial costs in responding to the crisis caused by Defendants' conduct.

485. The pattern of racketeering activity described above is currently ongoing and open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

D. Humboldt County Has Been Damaged by Defendants' RICO Violations

486. By reason of, and as a result of the conduct of the Enterprises and, in particular, their patterns of racketeering activity, Humboldt County has been injured in its business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs, as fully described above.

487. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and

proximately caused injuries and damages to Humboldt County, its community, and the public, and the County is entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

PUNITIVE DAMAGES

488. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

489. Through the egregious misconduct described above—including falsely advertising prescription opioids and deceiving regulators and the public regarding their compliance with their obligations to identify and report suspicious orders of prescription opioids—Defendants committed oppression, fraud, and malice. Defendants' conduct in creating the opioid epidemic is oppressive because Defendants' actions are despicable, were carried out in conscious disregard of Humboldt County's rights, and subjected the County to cruel and unusual hardship. Defendants' conduct is fraudulent because Defendants' made intentional misrepresentations and concealed material facts with the intention of depriving Humboldt County of property or legal rights or otherwise causing injury. Defendants' actions constitute malice because the despicable conduct was carried on by Defendants with a willful and conscious disregard of the rights or safety of others.

490. Pursuant to Civil Code § 3294 and common law, Humboldt County is entitled to punitive damages by way of example and to punish Defendants for their gross misconduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Humboldt County respectfully requests the Court order the following relief:

A. An Order that the conduct alleged herein violates the Unfair Competition Law;

B. An Order that the conduct alleged herein constitutes a public nuisance, under California law;

C. An Order that Defendants abate the public nuisance that they caused;

D. An Order that Defendants are negligent under California law;

E. An Order that Defendants have been unjustly enriched at Plaintiff's expense

under California law;

F. An Order that Defendants' conduct constitutes violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq*.;

G. An Order that Plaintiff is entitled to restitution and to recover all measure of damages permissible under the statutes identified herein and under common law;

H. An Order that Defendants are enjoined from the practices described herein;

I. An Order that judgment be entered against Defendants in favor of Plaintiff;

J. An Order that Plaintiff is entitled to punitive damages;

K. An Order that Plaintiff is entitled to attorneys' fees and costs pursuant to any applicable provision of law, including but not limited to under the Business and Professions Code; and

L. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all claims and of all issues so triable.

Dated July 18, 2018.

HUMBOLDT COUNTY

By: */s/ Jeffrey S. Blanck*
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